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PATENT
Attorney Docket No.: SCI-00100

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Group Art Unit: 3739
James L. Hobart et al.	Examiner: Shay, David M.
Serial No.: 09/018,104	**TRANSMITTAL LETTER**
Filed: February 3, 1998	162 North Wolfe Road Sunnyvale, California 94086 (408) 530-9700
For: **DUAL MODE LASER DELIVERY SYSTEM PROVIDING CONTROLLABLE DEPTH OF TISSUE ABLATION AND CORRESPONDING CONTROLLABLE DEPTH OF COAGULATION**	Customer Number 28960

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Enclosed please find an Appeal Brief submitted in triplicate in support of the patent owner's Notice of Appeal filed on August 5, 2005 for filing with the U.S. Patent and Trademark Office. Also attached is a check in the amount of $250.00 to cover the appeal brief filing fee.

The Commissioner is authorized to charge any additional fee or credit any overpayment to our Deposit Account No. 08-1275. **An originally executed duplicate of this transmittal is enclosed for this purpose.**

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Respectfully submitted,
HAVERSTOCK & OWENS LLP

Dated: October 5, 2005

By: Jonathan O. Owens
Jonathan O. Owens
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Attorneys for Applicants

CERTIFICATE OF MAILING (37 CFR§ 1.8(a))

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the U.S. Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the: Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450

HAVERSTOCK & OWENS LLP.

Date: 10-5-05 By: Jon O Owens

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Examiner: Shay, D.

APPEAL BRIEF

162 North Wolfe Road
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Alexandria, VA 22313-1450

Sir:

In furtherance of the Appellant's Notice of Appeal filed on August 5, 2005, this Appeal Brief is submitted herewith in triplicate. This Appeal Brief is submitted in support of the Appellant's Notice of Appeal, and further pursuant to the final rejection mailed on April 7, 2005, in which claims 1-14, 17-24 and 41-51 were rejected. The Appellants submit this Appeal Brief to the Board of Patent Appeals and Interferences in compliance with the requirements of 37 C.F.R. § 41.37. The Appellants contend that the rejections of Claims 1-14, 17-24 and 41-51 in this proceeding are in error and are overcome by this appeal.

I. REAL PARTY IN INTEREST

As the assignee of the entire right, title, and interest in the above-captioned patent application, the real party in interest in this appeal, is:

James L. Hobart
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Los Altos, CA 94022

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II. RELATED APPEALS AND INTERFERENCES

The Applicant is not aware of any other appeals or interferences related to the present application.

III. STATUS OF THE CLAIMS

Claims 1-14, 17-24 and 41-51 are pending in this case. Claims 15, 16 and 25-40 have been previously canceled. Claims 1, 11, and 41 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,125,922 to Dwyer (hereafter "Dwyer"); Claims 1-3, 8, 41, 43, 44 and 47-51 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,672,969 to Dew (hereinafter "Dew") in combination with, U.S. Patent No. 5,620,435 to Belkin et al. (hereinafter "Belkin et al.") and, the article entitled "Selective Photothermolysis: Precise Microsurgery by Selective Absorption of Pulsed Radiation" by R. Rox Anderson and John A. Parrish (hereinafter "Anderson et al."); Claims 1, 6, 7, 11-13, 17, 18, 41 and 44-46 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,098,426 to Sklar et al.

(hereinafter "Sklar et al.") in combination with Dwyer; Claims 4, 9, 10 and 42 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Dew in combination with Anderson et al., Belkin et al. and further in view of U.S. Patent No. 5,938,657 to Assa et al. (hereafter "Assa et al."); Claims 14 and 19-22 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Dew in combination with Anderson et al. and Belkin et al. and further in view of Sklar et al.; and Claims 23 and 24 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Dew in combination with Anderson et al., Belkin et al., Sklar et al. and further in view of Assa et al. Within this Appeal Brief, Claims 1-14, 17-24 and 41-51 are appealed. All prior art references relied on for applying these rejections are included in Section IX of this document, titled "Evidence Appendix."

IV. STATUS OF THE AMENDMENTS FILED AFTER FINAL REJECTION

No amendments have been filed subsequent to the Response mailed by the appellant on July 14, 2004, in response to a Final Office Action mailed on May 14, 2004. The present condition of the claims is as listed in the Amendment and Response to Office Action, which was mailed by the Appellants on July 14, 2004.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The present invention is directed to a medical laser that uses laser pulses from each of the plurality of laser sources and combines the pulses to form a laser output of the combined pulses while the medical laser is in at least one of ablation mode or coagulation mode. In order to accomplish this goal, a galvanometer is preferably used to rapidly switch between the pulses from each of the laser sources. Each of the lasers emit laser light having the same wavelength. Reference numbers for elements recited in the claims, illustrated in the figures and supported in the present specification have been added below.

The elements recited in Claim 1 are illustrated in Fig. 3 and described in the corresponding text of the Specification on page 7, lines 8-28 and page 8, lines 1-2. Claim 1 recites a medical laser delivery apparatus for delivering a series of laser pulses having a wavelength, the medical laser delivery apparatus including non-ablative laser pulses for directing to an area of tissue to be treated and generating a region of coagulation to a controllable coagulation depth under a surface of the area of tissue, the apparatus comprising a laser source (**31**) for generating the series of laser pulses including the non-ablative laser pulses to be

delivered to the area of tissue to be treated in order to raise a temperature at the surface of the area of tissue to be treated to a temperature sufficient to generate coagulation at the coagulation depth when the laser source is in a coagulation mode, wherein the laser source (**31**) comprises two or more lasers (**32, 35**) that combines the series of laser pulses (**33, 35**) from the two or more lasers (**32, 35**).

The elements recited in Claim 11 are illustrated in Figs. 3-4 and described in the corresponding text of the Specification on page 7, lines 8-28 and page 8, lines 1-14. Claim 11 recites a medical laser comprising a laser source having two or more pulsed lasers (**32, 35**) for generating pulses (**33, 35**) of laser light having a wavelength, wherein a series of the pulses of laser light are combined from the laser source (**31**) for generating a single laser output (**37**) having a predetermined absorption, wherein the predetermined absorption forms a predetermined coagulation depth and a laser control system (**Fig. 4**) coupled to the laser source for controlling the laser source (**31**) to deliver the laser output (**37**) to a target area (**58**).

The elements recited in Claim 17 are illustrated in Figs. 3-4 and described in the corresponding text of the Specification on page 7, lines 8-28 and page 8, lines 1-14. Claim 17 recites a medical laser delivery apparatus for treating an area of tissue comprising a laser source (**31**) having a first laser (**32**) and a second laser (**34**) each of which generate laser pulses (**33, 35**) having a wavelength, the laser source (**31**) being configured to combine laser pulses of the first laser (**32**) and the second laser (**34**) to form a single laser output (**37**) by a combining apparatus (**36**) for delivering a series of laser pulses each having a strength and a duration to ablate or coagulate the area of tissue (**58**) being treated, a laser delivery system (**38**) coupled to the laser source (**31**) for delivering the laser pulses from the laser source (**31**) to the area of tissue (**58**) being treated and a control system (**Fig. 4**) for selecting the rate and fluence of the laser pulses, the control system coupled to the laser source for controlling generation of the laser pulses from the laser source, wherein the laser source operates in both an ablation mode and a coagulation mode such that when in the ablation mode, the strength and duration of the laser pulses are sufficient to ablate tissue at the area of tissue being treated to a controllable ablation depth and when in the coagulation mode, the strength and duration of the laser pulses are sufficient to generate a coagulation region having a controllable coagulation depth within the tissue remaining at the area of tissue being treated without ablating any tissue.

The elements recited in Claim 41 are illustrated in Fig. 3 and described in the corresponding text of the Specification on page 7, lines 8-28 and page 8, lines 1-2. Claim 41

recites a dual mode medical laser system, for sequentially ablating and coagulating a region of target tissue with ablation laser pulses followed by coagulation laser pulses, the dual mode medical laser system comprising a laser source (**31**) comprising a first laser (**32**) and a second laser (**34**) for generating a first set of laser pulses (**33**) and a second set of laser pulses (**35**) at a wavelength means to combine pulses (**31**) of the first set of laser pulses (**33**) and the second set of laser pulses (**35**) to provide a single laser output (**37**), the single laser output (**37**) being capable of coagulating tissue with the system in a coagulation mode and ablating tissue with the system in an ablating mode and means to direct (**38**) the single laser output (**37**) to the region of the target tissue (**58**).

The elements recited in Claim 50 are illustrated in Fig. 3 and described in the corresponding text of the Specification on page 7, lines 8-28 and page 8, lines 1-2. Claim 50 recites a medical laser delivery apparatus for delivering a series of laser pulses (**37**) having a wavelength, the medical laser delivery apparatus including non-ablative laser pulses for directing to an area of tissue (**58**) to be treated and generating a region of coagulation to a controllable coagulation depth under a surface of the area of tissue (**58**), the apparatus comprising a laser source (**31**) for generating the series of laser pulses including the non-ablative laser pulses to be delivered to the area of tissue (**58**) to be treated in order to raise a temperature at the surface of the area of tissue to be treated to a temperature sufficient to generate coagulation at the coagulation depth when the laser source (**31**) is in a coagulation mode, wherein the laser source (**31**) comprises two or more lasers (**32, 34**), the medical laser delivery apparatus further comprising a galvanometer (**36**) that combines the series of laser pulses from the two or more lasers (**32, 34**) into a single laser output (**37**) by switching between laser outputs (**33, 35**) from the two or more lasers (**32, 34**).

The elements recited in Claim 51 are illustrated in Figs. 3-4 and described in the corresponding text of the Specification on page 7, lines 8-28 and page 8, lines 1-14. 51. Claim 51 recites a medical laser comprising a laser source (**31**) having two or more pulsed lasers (**32, 34**) for generating laser outputs (**33, 35**) having a wavelength, wherein a series of the pulses of laser light are combined into a single laser output (**37**) by switching between the laser outputs (**33, 35**) with a galvanometer (**36**), the single laser output (**37**) having a predetermined absorption, wherein the predetermined absorption forms a predetermined coagulation depth and a laser control system (**Fig. 4**) coupled to the laser source for controlling the laser source (**31**) to deliver the laser output to a target area.

VI. GROUNDS OF REJECTION

The issues presented by the appellant for review by the Board of Patent Appeals and Interferences are as follows:

1. Whether the Claims 1, 11, and 41 are properly rejected under 35 U.S.C. § 102(b) as being anticipated by Dwyer.
2. Whether the Claims 1-3, 8, 41, 43, 44 and 47-51 are properly rejected under 35 U.S.C. § 103(a) as being unpatentable over Dew in combination Belkin et al. and Anderson et al.
3. Whether the Claims 1, 6, 7, 11-13, 17, 18, 41 and 44-46 are properly rejected under 35 U.S.C. § 103(a) as being unpatentable over Sklar et al. in combination with Dwyer.
4. Whether the Claims 4, 9, 10 and 42 are properly rejected under 35 U.S.C. § 103(a) as being unpatentable over Dew in combination with Anderson et al., Belkin et al. and further in view of Assa et al.
5. Whether the Claims 14 and 19-22 are properly rejected under 35 U.S.C. § 103(a) as being unpatentable over Dew in combination with Anderson et al. and Belkin et al. and further in view of Sklar et al.
6. Whether the Claims 23 and 24 are properly rejected under 35 U.S.C. § 103(a) as being unpatentable over Dew in combination with Anderson et al., Belkin et al., Sklar et al. and further in view of Assa et al.

VII. ARGUMENT

A. Claims 1, 11 and 41 are Patentable over Dwyer

Claims 1, 11 and 41 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Dwyer. It is the Appellant's position that the rejections of the claims is predicated on an overly broad interpretation of the teachings of Dwyer. The medical laser system of Dwyer does not have the structural features of the claimed invention and is not functionally the same as the claimed invention.

Dwyer teaches an apparatus with two lasers producing two different wavelengths. An operator can choose which wavelength is selected by turning on the appropriate laser and shutting off the appropriate laser. However, it not feasible to alternate between pulses or sets of pulses, with an apparatus such as taught by Dwyer, in the time frame required to perform a coagulation or ablation operation on a target area tissue as recited in the claims of the present invention. The Examiner's reason for disregarding these distinctions has been stated as Dwyer teaches a medical laser that can ablate and coagulate tissue and the switching between the two functions can be done quickly.

While, the present invention is directed to a medical laser that has a plurality of laser sources and which can change between ablation and coagulation mode, these are **not** the only limitations recited in the claims. The present invention is also directed to a medical laser that uses laser pulses from each of the plurality of laser sources and combines the pulses to form a laser output of the combined pulses while the medical laser is in at least one of ablation mode or coagulation mode. In order to accomplish this goal, a galvanometer is preferably used to rapidly switch between the pulses from each of the laser sources. Applicants contend that the medical laser system of Dwyer can not operate to switch between laser sources on a pulse time scale, such that the pulses from both lasers can be combined while operating in at least one of the ablation mode and coagulation mode. Appellants have made numerous attempts to amend each of the independent Claims 1, 11 and 41 to more clearly recite these distinguishing features.

For example, Appellants have amended the independent Claim 1 during prosecution to recite a medical laser delivery apparatus for delivering a series of laser pulses having a wavelength, in order to clearly state that the series of laser pulses have laser light at the wavelength. The Examiner has argued that "comprising-type" claim language allows more than one wavelength to exist in the laser output. It is further stated that the originally filed disclosure

does not provide support for both lasers to produce pulses of the same wavelength. The Appellants contend that while the laser light can include more than one wavelength, that does not preclude or render irrelevant the limitation of laser pulses from more than one laser source having the wavelength, (viz. the same wavelength). Further, it is a fact of physics that lasers of the "same kind" by definition produce laser light of the same wavelength. Laser light is a property of the lasing material and lasers made from the same material, will lase with the same wavelength or wavelengths. Accordingly, in the absence of any modifying optics and/or filters, pulses from two or more lasers of the same kind will have laser light at the same wavelength and can, therefore, be combined to produce a laser output having the wavelength. Secondly, the Appellants contend that there is clear support in the text of the specification as well as Fig. 4 for these claimed limitations.

> The laser system of the preferred embodiment of the present invention is schematically illustrated in Figure 3. The laser generation system housing 30 includes the laser source 31 from which the laser beam 37 is provided. The laser source 31 preferably includes two erbium lasers 32 and 34 which generate the laser beams 33 and 35, respectively. Alternatively, any other appropriate short penetration length laser source can be used within the system of the present invention. The two laser beams 33 and 35 are combined into a single laser output 37 by the galvanometer 36 which switches between the two laser outputs 33 and 35. The galvanometer 36 then provides the laser output 37 from the laser source 31. [Present Specification, Page 7, lines 8-15]

In summary, Dwyer teaches a medical laser system with lasers that operate at two different wavelengths. In use, an operator can switch between lasers to produce two corresponding laser outputs, one with a first wavelength for ablation and one with a second wavelength for coagulation. However, Dwyer does not teach or suggest combining pulses from the same kind of laser, the pulses having a *wavelength* and wherein the combined pulses produce a laser output at the *wavelength* while operating in at least one of ablation mode or coagulation mode. Appellants contend that these as well as a number of other distinguishing features are clearly recited in each of the independent Claims 1, 11, 17, 41, 50 and 51.

Claims 1, 11 and 41

The independent Claim 1 is directed to a medical laser delivery apparatus for delivering a series of laser pulses having *a wavelength*, the medical laser delivery apparatus including non-ablative laser pulses for directing to an area of tissue to be treated and generating a region of coagulation to a controllable coagulation depth under a surface of the area of tissue. The

apparatus of Claim 1 comprises a laser source for generating the series of laser pulses including the non-ablative laser pulses to be delivered to the area of tissue to be treated in order to raise a temperature at the surface of the area of tissue to be treated to a temperature sufficient to generate coagulation at the coagulation depth when the laser source is in a coagulation mode. The laser source comprises two or more lasers that combine the series of laser pulses from the two or more lasers. As discussed above, Dwyer fails to teach a medical laser delivery apparatus which has a laser source with two or more lasers having *a wavelength* that are combined to form a single output to generate conditions for ablation and coagulation. For at least these reasons, the independent Claim 1 is allowable over the teachings of Dwyer.

The independent Claim 11 is directed to a medical laser comprising a laser source having two or more pulsed lasers for generating pulses of laser light having *a wavelength*, wherein a series of the pulses of laser light are combined from the laser source for generating a single laser output having a predetermined absorption, wherein the predetermined absorption forms a predetermined coagulation depth and a laser control system coupled to the laser source for controlling the laser source to deliver the laser output to a target area. As discussed above, Dwyer fails to teach a medical laser delivery apparatus which has a laser source with two or more lasers having *a wavelength* that are combined to form a single output to generate conditions for ablation and coagulation. For at least these reasons, the independent Claim 11 is allowable over the teachings of Dwyer.

The independent Claim 41 is directed to a dual mode medical laser system, for sequentially ablating and coagulating a region of target tissue with ablation laser pulses followed by coagulation laser pulses. The dual mode medical laser system of Claim 41 comprises a laser source comprising a first laser and a second laser for generating a first set of laser pulses and a second set of laser pulses at *a wavelength*, means to combine pulses of the first set of laser pulses and the second set of laser pulses to provide a single laser output, the single laser output being capable of coagulating tissue with the system in a coagulation mode and ablating tissue with the system in an ablating mode and means to direct the single laser output to the region of the target tissue. As discussed above, Dwyer fails to teach a system capable of coagulating tissue with the system in a coagulation mode, and ablating tissue with the system in ablation mode which combines laser pulses having *a wavelength* from multiple lasers to generate a single laser output. For at least these reasons, the independent Claim 41 is allowable over the teachings of Dwyer.

B. Claims 1-3, 8, 41, 43, 44 and 47-51 are Patentable over Dew in view of Belkin et al. and Anderson et al.

Claims 1-3, 8, 41, 43, 44 and 47-51 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Dew in combination with Belkin et al. and Anderson et al. Appellants respectfully traverse the rejection of Claims 1-3, 8, 41, 43, 44 and 47-51 under 35 U.S.C. § 103(a) as being unpatentable over Dew in combination with Belkin et al. and Anderson et al. for the following reasons.

Dew teaches a laser healing method to effect wound closure and reconstruction of biological tissue. Optical energy is applied to produce thermal heating of biological tissue to a degree suitable for denaturing the tissue proteins such that the collagenous elements of the tissue form a biological glue to seal and reconstruct the tissue being heated. [Dew, Abstract] The system of Dew includes a laser 20. Dew teaches a marker laser 30 which is co-aligned with the infrared beam of the laser 20. Further, Dew teaches that an auxiliary source of optical energy 50 can be incorporated into the apparatus to emit radiation having a wavelength which is intensely absorbed by biological tissue. Dew does not teach a medical laser with a laser source having two or more lasers having a wavelength, wherein pulses from the two or more lasers are combined for generating a laser output at the wavelength while operating in at least one of the ablation mode and coagulation mode.

Belkin et al. teaches a method for welding ocular tissues to each other using a carbon dioxide laser. [Belkin et al., col. 2, lines 35-44] Belkin et al. do not teach a medical laser with a laser source with two or more lasers. Belkin et al. do not teach a medical laser with a laser source having two or more lasers having a wavelength, wherein pulses from the two or more lasers are combined for generating a laser output at the wavelength while operating in at least one of the ablation mode and coagulation mode.

Anderson et al. teach a scheme for confining thermally mediated radiation damage to chosen pigmented targets. [Anderson et al., p. 524] The technique relies on selective absorption of a brief radiation pulse to generate and confine heat at certain pigmented targets. [Anderson et al., p. 524] Anderson et al. do not teach a medical laser with a laser source having two or more lasers having a wavelength, wherein pulses from the two or more lasers are combined for generating a laser output at the wavelength while operating in at least one of the ablation mode and coagulation mode.

Neither Dew, Belkin, Anderson et al., nor their combination teach or suggest a medical laser with a laser source having two or more lasers having a wavelength, wherein pulses from the

two or more lasers are combined for generating a laser output at the wavelength while operating in at least one of the ablation mode and coagulation mode or means for combining pulses from two or more lasers. These features as well as other distinguishing features are recited in the independent Claims 1, 41, 50 and 51. For at least these reasons, the independent Claims 1, 41, 50 and 51 are allowable over the teachings of Dew, Belkin et al., Anderson et al. and their combination.

Claims 1, 41, 50 and 51

Specifically, the independent Claim 1 recites a medical laser delivery apparatus for delivering a series of laser pulses having *a wavelength*, the medical laser delivery apparatus including non-ablative laser pulses for directing to an area of tissue to be treated and generating a region of coagulation to a controllable coagulation depth under a surface of the area of tissue, the apparatus comprising a laser source for generating the series of laser pulses including the non-ablative laser pulses to be delivered to the area of tissue to be treated in order to raise a temperature at the surface of the area of tissue to be treated to a temperature sufficient to generate coagulation at the coagulation depth when the laser source is in a coagulation mode, wherein the laser source comprises two or more lasers that combines the series of laser pulses from the two or more lasers. As discussed above, neither Dew, Belkin et al., Anderson et al. nor their combination teach or make obvious a laser delivery apparatus for delivering a series of laser pulses having *a wavelength* comprising a laser source with two or more lasers that combines a series of laser pulses from the two or more lasers. For at least these reasons, the independent Claim 1 is allowable over the teachings of Dew, Belkin, Anderson and their combination.

Claims 2, 3 and 8 are all dependent on the independent Claim 1. As described above, the independent Claim 1 is allowable over the teachings of Dew, Belkin et al., Anderson et al. and their combination. Accordingly, Claims 2, 3 and 8 are all also allowable as being dependent upon an allowable base claim.

The independent Claim 41 is directed to a dual mode medical laser system, for sequentially ablating and coagulating a region of target tissue with ablation laser pulses followed by coagulation laser pulses, the dual mode medical laser system comprising a laser source comprising a first laser and a second laser for generating a first set of laser pulses and a second set of laser pulses at *a wavelength*, means to combine pulses of the first set of laser pulses and the second set of laser pulses to provide a single laser output, the single laser output being capable of coagulating tissue with the system in a coagulation mode and ablating tissue with the system in

an ablating mode and means to direct the single laser output to the region of the target tissue. As discussed above, neither Dew, Belkin et al., Anderson et al. nor their combination teach or make obvious a medical laser system for delivering a series of laser pulses having comprising a laser source comprising a first laser and a second laser for generating a first set of laser pulses and a second set of laser pulses at *a wavelength*; means to combine pulses of the first set of laser pulses and the second set of laser pulses to provide a single laser output, the single laser output being capable of coagulating tissue with the system in a coagulation mode and ablating tissue with the system in an ablating mode. For at least these reasons, the independent Claim 41 is allowable over the teachings of Dew, Belkin et al., Anderson et al. and their combination.

Claims 43, 44 and 47-49 are all dependent on the independent Claim 41. As described above, the independent Claim 41 is allowable over the teachings of Dew, Belkin et al., Anderson et al. and their combination. Accordingly, Claims 43, 44 and 47-49 are also all allowable as being dependent upon an allowable base claim.

The independent Claim 50 is directed to a medical laser delivery apparatus for delivering a series of laser pulses having a wavelength, the medical laser delivery apparatus including non-ablative laser pulses for directing to an area of tissue to be treated and generating a region of coagulation to a controllable coagulation depth under a surface of the area of tissue, the apparatus comprising a laser source for generating the series of laser pulses including the non-ablative laser pulses to be delivered to the area of tissue to be treated in order to raise a temperature at the surface of the area of tissue to be treated to a temperature sufficient to generate coagulation at the coagulation depth when the laser source is in a coagulation mode, wherein the laser source comprises two or more lasers, the medical laser delivery apparatus further comprising a galvanometer that combines the series of laser pulses from the two or more lasers into a single laser output by switching between laser outputs from the two or more lasers. As discussed above, neither Dew, Belkin et al., Anderson et al. nor their combination teach or make obvious a medical laser delivery apparatus for delivering a series of laser pulses having a wavelength from a laser source comprising two or more lasers, and a galvanometer that combines the series of laser pulses from the two or more lasers into a single laser output by switching between laser outputs from the two or more lasers. For at least these reasons, the independent Claim 50 is allowable over the teachings of Dew, Belkin et al., Anderson et al. and their combination.

The independent Claim 51 is directed to a medical laser comprising a laser source having two or more pulsed lasers for generating laser outputs having a wavelength, wherein a series of the pulses of laser light are combined into a single laser output by switching between the laser

outputs with a galvanometer, the single laser output having a predetermined absorption, wherein the predetermined absorption forms a predetermined coagulation depth and a laser control system coupled to the laser source for controlling the laser source to deliver the laser output to a target area. As discussed above, neither Dew, Belkin et al., Anderson et al. nor their combination teach or make obvious a medical laser comprising a laser source having two or more pulsed lasers and a galvanometer that combines the series of laser pulses from the two or more lasers into a single laser output by switching between laser outputs. For at least these reasons, the independent Claim 51 is allowable over the teachings of Dew, Belkin et al., Anderson et al. and their combination.

C. Claims 1, 6, 7, 11-13, 17, 18, 41 and 44-46 are Patentable over Sklar et al. in view of Dwyer.

Claims 1, 6, 7, 11-13, 17, 18, 41 and 44-46 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Sklar et al. in view of Dwyer. The Appellants respectfully traverse the rejection of Claims 1, 6, 7, 11-13, 17, 18, 41 and 44-46 under 35 U.S.C. § 103(a) as being unpatentable over Sklar et al. in view Dwyer for the following reasons.

Sklar et al. teach a system and method for accurately controlling and positioning laser sources, specifically during surgery. According to Sklar et al. "a limiting factor to the duration of the operation under these procedures (viz. Prior Art procedures) is the surgeon's reaction time while focusing on the target and the patients movement while the surgeon is trying to find the target and react to the target recognition by firing the laser. [Sklar et al., column 5, lines 13-19] In view of these prior art limitations, Sklar et al. teach a system for performing precision laser surgery which includes an imaging system for providing a surgeon with precision tracking and topographical information regarding the surgical target area. [Sklar et al., Abstract] Sklar et al. state that "it is well appreciated that the limitations on the achievable accuracy and control of laser surgical instruments today is no longer paced by the development of laser technology, but by the imaging and tracking technologies needed to efficiently use the laser." [Sklar et al., column 2, lines 39-43]

In other words the teachings of Sklar et al. are directed to laser tracking and not a laser delivery system in accordance with the teachings of the present Application. Even if the teachings of Sklar et al. in combination with the teachings of Dwyer were appropriate, Sklar et al. do not teach a medical laser with a laser source having two or more lasers having a wavelength,

wherein pulses from the two or more lasers are combined for generating a laser output at the wavelength while operating in at least one of the ablation mode and coagulation mode.

Further, it is noted that from the description that the tracking system of Sklar et al. can be used with any number of laser sources. Sklar et al. state that "the therapeutic laser may be a frequency multiplied solid state laser which may be either flash lamp or diode pumped, or an argon, argon pumped dye, excimer, excimer pumped dye, nitrogen, nitrogen pumped dye, or any host of different lasers or combinations thereof." [Sklar et al., column 16, lines 60-68] The mere recitation of a "combination" of lasers does not suggest or teach the particular configuration of lasers claimed in the present application. The recitation of a "combination" of lasers is interpretable to mean independently operable lasers, combination lasers and pumping lasers and any other imaginable "combination."

As discussed above, Dwyer teaches an apparatus with two lasers producing two different wavelengths. An operator can choose which wavelength is selected by turning on the appropriate laser and shutting off the appropriate laser. However, it not feasible to alternate between pulses or sets of pulses, with an apparatus such as taught by Dwyer, in the time frame required to perform a coagulation or ablation operation on a target area tissue as recited in the claims of the present invention. The Examiner's reason for disregarding these distinctions has been stated as Dwyer teaches a medical laser that can ablate and coagulate tissue and the switching between the two functions can be done quickly.

As further discussed above, the present invention is directed to a medical laser that has a plurality of laser sources and which can change between ablation and coagulation mode, these are **not** the only limitations recited in the claims. The present invention is also directed to a medical laser that uses laser pulses from each of the plurality of laser sources and combines the pulses to form a laser output of the combined pulses while the medical laser is in at least one of ablation mode or coagulation mode. In order to accomplish this goal, a galvanometer is preferably used to rapidly switch between the pulses from each of the laser sources. Applicants contend that the medical laser system of Dwyer can not operate to switch between laser sources on a pulse time scale, such that the pulses from both lasers can be combined while operating in at least one of the ablation mode and coagulation mode.

Neither Sklar et al., Dwyer nor their combination teaches or suggests combining laser pulses from a laser source comprising two or more lasers having a wavelength to generate a single laser output for coagulating or ablating tissue. These features, as well as other

distinguishing features, are recited in the independent Claims 1, 11, 17 and 41. For at least these reasons, the independent Claims 1, 11, 17 and 41 are allowable over the teachings of Sklar et al., Dwyer and their combination.

Claims 1, 11, 17 and 41

Specifically, the independent Claim 1 recites a medical laser delivery apparatus for delivering a series of laser pulses having *a wavelength*, the medical laser delivery apparatus including non-ablative laser pulses for directing to an area of tissue to be treated and generating a region of coagulation to a controllable coagulation depth under a surface of the area of tissue, the apparatus comprising a laser source for generating the series of laser pulses including the non-ablative laser pulses to be delivered to the area of tissue to be treated in order to raise a temperature at the surface of the area of tissue to be treated to a temperature sufficient to generate coagulation at the coagulation depth when the laser source is in a coagulation mode, wherein the laser source comprises two or more lasers that combines the series of laser pulses from the two or more lasers. As discussed above, neither Sklar et al., Dwyer nor their combination teach or make obvious a laser delivery apparatus for delivering a series of laser pulses having *a wavelength* comprising a laser source with two or more lasers that combines a series of laser pulses from the two or more lasers. For at least these reasons, the independent Claim 1 is allowable over the teachings of Sklar et al., Dwyer and their combination.

Claims 6 and 7 are both dependent on the independent Claim 1. As described above, the independent Claim 1 is allowable over the teachings of Sklar et al., Dwyer and their combination. Accordingly, Claims 6 and 7 are both also allowable as being dependent upon an allowable base claim.

The independent Claim 11 is directed to a medical laser comprising a laser source having two or more pulsed lasers for generating pulses of laser light having *a wavelength*, wherein a series of the pulses of laser light are combined from the laser source for generating a single laser output having a predetermined absorption, wherein the predetermined absorption forms a predetermined coagulation depth and a laser control system coupled to the laser source for controlling the laser source to deliver the laser output to a target area. As discussed above, neither Sklar et al., Dwyer nor their combination teach or make obvious a medical laser comprising a laser source having two or more pulsed lasers for generating pulses of laser light having *a wavelength*. For at least these reasons, the independent Claim 11 is allowable over the teachings of Sklar et al., Dwyer and their combination.

Claims 12 and 13 are both dependent on the independent Claim 11. As described above, the independent Claim 11 is allowable over the teachings of Sklar et al., Dwyer and their combination. Accordingly, Claims 12 and 13 are also both allowable as being dependent upon an allowable base claim.

The independent Claim 17 is directed to a medical laser delivery apparatus for treating an area of tissue comprising a laser source having a first laser and a second laser each of which generate laser pulses having *a wavelength*, the laser source being configured to combine laser pulses of the first laser and the second laser to form a single laser output by a combining apparatus for delivering a series of laser pulses each having a strength and a duration to ablate or coagulate the area of tissue being treated a laser delivery system coupled to the laser source for delivering the laser pulses from the laser source to the area of tissue being treated and a control system for selecting the rate and fluence of the laser pulses, the control system coupled to the laser source for controlling generation of the laser pulses from the laser source, wherein the laser source operates in both an ablation mode and a coagulation mode such that when in the ablation mode, the strength and duration of the laser pulses are sufficient to ablate tissue at the area of tissue being treated to a controllable ablation depth and when in the coagulation mode, the strength and duration of the laser pulses are sufficient to generate a coagulation region having a controllable coagulation depth within the tissue remaining at the area of tissue being treated without ablating any tissue. As discussed above, neither Sklar et al., Dwyer nor their combination teach or make obvious medical laser delivery apparatus for treating an area of tissue comprising a laser source having a first laser and a second laser each of which generate laser pulses having *a wavelength*, the laser source being configured to combine laser pulses of the first laser and the second laser to form a single laser output. For at least these reasons, the independent Claim 17 is allowable over the teachings of Sklar et al., Dwyer and their combination.

Claim 18 is dependent on the independent Claim 17. As described above, the independent Claim 17 is allowable over the teachings of Sklar et al., Dwyer and their combination. Accordingly, Claim 18 is also allowable as being dependent upon an allowable base claim.

The independent Claim 41 is directed to a dual mode medical laser system, for sequentially ablating and coagulating a region of target tissue with ablation laser pulses followed by coagulation laser pulses, the dual mode medical laser system comprising a laser source comprising a first laser and a second laser for generating a first set of laser pulses and a second

set of laser pulses at *a wavelength*; means to combine pulses of the first set of laser pulses and the second set of laser pulses to provide a single laser output, the single laser output being capable of coagulating tissue with the system in a coagulation mode and ablating tissue with the system in an ablating mode and means to direct the single laser output to the region of the target tissue. As discussed above, neither Sklar et al., Dwyer nor their combination teach or make obvious a medical laser system for delivering a series of laser pulses having a laser source comprising a first laser and a second laser for generating a first set of laser pulses and a second set of laser pulses at *a wavelength*; means to combine pulses of the first set of laser pulses and the second set of laser pulses to provide a single laser output, the single laser output being capable of coagulating tissue with the system in a coagulation mode and ablating tissue with the system in an ablating mode. For at least these reasons, the independent Claim 41 is allowable over the teachings of Dew, Belkin, Anderson and their combination.

Claims 44-46 are all dependent on the independent Claim 41. As described above, the independent Claim 41 is allowable over the teachings of Sklar et al., Dwyer and their combination. Accordingly, Claims 44-46 are also all allowable as being dependent upon an allowable base claim.

D. Claims 4, 9, 10 and 42 are Patentable over Dew in view of Anderson et al., Belkin et al. and Assa et al.

Claims 4, 9, 10 and 42 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Dew in view of Anderson et al., Belkin et al., and Assa et al. The Appellants respectfully traverse the rejection of Claims 4, 9, 10 and 42 under 35 U.S.C. § 103(a) as being unpatentable over Dew in view of Anderson et al., Belkin et al., and Assa et al. for the following reasons.

Assa et al. teach an apparatus for delivering energy with a continuous output and can not be combined with Dew, Anderson et al. or Belkin et al., either singularly or in combination, to teach the combination of features taught and claimed in the instant application. Again, the inordinate number of combined references is inconsistent with establishing a prima facie case of obviousness and there is no hint, teaching or suggestion in the prior art to combine the references in a way which would produce the invention as claimed in the instant application. Further, neither Dew, Anderson et al., Belkin et al., Assa et al. nor their combination teaches or suggests combining laser pulses from a laser source comprising two or more lasers having a wavelength to generate a single laser output while in at least one of coagulating or ablating mode.

Claims 4, 9 and 10 are all dependent on the independent Claim 1, and Claim 42 is dependent on the independent Claim 41. As described above, the independent Claims 1 and 41 are both allowable over the teachings Dew, Belkin et al., Anderson et al. and their combination. Accordingly, Claims 4, 9, 10 and 42 are also all allowable as being dependent upon allowable base claims.

E. Claims 14 and 19-22 are Patentable over Dew in view of Anderson et al., Belkin et al. and Sklar et al.

Claims 14 and 19-22 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Dew in view of Anderson et al., Belkin et al., and Sklar et al. The Appellants respectfully traverse the rejection of Claims 14 and 19-22 under 35 U.S.C. § 103(a) as being unpatentable over Dew in view of Anderson et al., Belkin et al., and Sklar et al. for the following reasons.

As previously described neither Dew, Anderson et al., Belkin et al., Sklar et al. nor their combination teach or suggest a medical laser comprising a laser source having two or more pulsed lasers for generating pulses of laser light having *a wavelength,* such as recited in the independent Claim 11. For at least these reasons, the independent Claim 11 is allowable over the teachings of Dew, Anderson et al., Belkin et al., Sklar et al. and their combination.

Claims 14 and 19-22 are all dependent on the independent Claim 11. As described above the independent Claim 11 is allowable over the teaching of Sklar et al., Dwyer and their combination. Accordingly, Claims 14 and 19-22 are also all allowable as being dependent on an allowable base claim.

F. Claims 23 and 24 are Patentable over Dew in view of Anderson et al., Belkin et al., Sklar et al. and Assa et al.

Claims 23 and 24 both stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Dew in view of Anderson et al., Belkin et al., Sklar et al. and Assa et al. The Appellants respectfully traverse the rejection of Claims 23 and 24 under 35 U.S.C. § 103(a) as being unpatentable over Dew in view of Anderson et al., Belkin et al., Sklar et al. and Assa et al. for the following reasons.

Again, neither Dew, Anderson et al., Belkin et al., Sklar et al., Assa et al., nor their combination teach or suggest a medical laser delivery apparatus for treating an area of tissue comprising a laser source having a first laser and a second laser each of which generate laser pulses having *a wavelength*, the laser source being configured to combine laser pulses of the first

laser and the second laser to form a single laser output, such as recited in the independent Claim 17. For at least these reasons, the independent Claim 17 is allowable over the teachings of Dew, Anderson et al., Belkin et al., Sklar et al., Assa et al. and their combination.

Claims 23 and 24 are both dependent on the independent Claim 17. As described above, the independent Claim 17 is allowable over the teachings of Sklar et al., Dwyer and their combination. Accordingly, Claims 23 and 24 are both also allowable as being dependent upon an allowable base claim.

G. CONCLUSION

Each of the independent Claims 1, 11, 17, 41, 50 and 51 recite limitations that require multiple laser outputs having "the same wavelength" from multiple lasers be combined to generate a single laser output to treat a target tissue. Appellants contents that these features are neither taught or suggested by the prior art and, therefore, each of the independent Claim 1, 11, 17, 41, 50 and 51 are in condition for allowance. Claims 2-10, 12-14, 18-24 and 42-49 are all also in condition for allowance as being dependent upon an allowable base claim.

Respectfully submitted,
HAVERSTOCK & OWENS LLP

Dated: October 5, 2005

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CERTIFICATE OF MAILING (37 CFR§ 1.8(a))

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the U.S. Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the: Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450

HAVERSTOCK & OWENS LLP.

Date: 10-5-05 By: Jon O. Owens

VIII. CLAIMS APPENDIX

Claims Under Appeal

Listing of Claims:

1. A medical laser delivery apparatus for delivering a series of laser pulses having a wavelength, the medical laser delivery apparatus including non-ablative laser pulses for directing to an area of tissue to be treated and generating a region of coagulation to a controllable coagulation depth under a surface of the area of tissue, the apparatus comprising a laser source for generating the series of laser pulses including the non-ablative laser pulses to be delivered to the area of tissue to be treated in order to raise a temperature at the surface of the area of tissue to be treated to a temperature sufficient to generate coagulation at the coagulation depth when the laser source is in a coagulation mode, wherein the laser source comprises two or more lasers that combines the series of laser pulses from the two or more lasers.

2. The medical laser delivery apparatus as claimed in claim 1 wherein the series of laser pulses are focussed to the target tissue through an articulated arm feature.

3. The medical laser delivery apparatus as claimed in claim 2 wherein the articulated arm feature comprises one or more refocussing optics for refocussing the laser pulses as they travel through the articulated arm feature.

4. The medical laser delivery apparatus as claimed in claim 3 wherein the laser delivery system further comprises a scanning handpiece at an end of the articulated arm feature for guiding the series of one or more non-ablative laser pulses to the area of tissue being treated.

5. The medical delivery apparatus as claimed in claim 4 wherein the refocussing optics are simple convex lenses.

6. The medical laser delivery apparatus as claimed in claim 1 further comprising a graphical user interface through which a user selects the coagulation depth and/or fluence.

7. The medical laser delivery apparatus as claimed in claim 6 wherein the laser source also has an ablation mode wherein it generates laser pulses of a strength and duration to ablate tissue at the area of tissue being treated to an ablation depth and the user selects the ablation depth through the graphical user interface.

8. The medical laser delivery apparatus as claimed in claim 1 wherein the apparatus is configured to generate laser pulses with short penetration depths.

9. The medical laser delivery apparatus as claimed in claim 8 wherein the two or more lasers are erbium lasers.

10. The medical laser delivery apparatus as claimed in claim 9 wherein the erbium lasers are Er:YAG lasers.

11. A medical laser comprising:

a. a laser source having two or more pulsed lasers for generating pulses of laser light having a wavelength, wherein a series of the pulses of laser light are combined from the laser source for generating a single laser output having a predetermined absorption, wherein the predetermined absorption forms a predetermined coagulation depth; and

b. a laser control system coupled to the laser source for controlling the laser source to deliver the laser output to a target area.

12. The medical laser as claimed in claim 11 further comprising a graphical user interface through which a user selects a depth of the coagulation region formed by the coagulative laser pulses.

13. The medical laser as claimed in claim 12 further comprising a laser delivery system coupled to the laser source for delivering the laser beam from the laser source to an area of tissue to be treated.

14. The medical laser as claimed in claim 13 wherein the laser delivery system comprises an articulated arm and one or more refocussing optics for refocussing the laser beam as it travels through the arm.

Claims 15-16 (Canceled).

17. A medical laser delivery apparatus for treating an area of tissue comprising:

a. a laser source having a first laser and a second laser each of which generate laser pulses having a wavelength, the laser source being configured to combine laser pulses of the first laser and the second laser to form a single laser output by a combining apparatus for delivering a series of laser pulses each having a strength and a duration to ablate or coagulate the area of tissue being treated;

b. a laser delivery system coupled to the laser source for delivering the laser pulses from the laser source to the area of tissue being treated; and

c. a control system for selecting the rate and fluence of the laser pulses, the control system coupled to the laser source for controlling generation of the laser pulses from the laser source, wherein the laser source operates in both an ablation mode and a coagulation mode such that when in the ablation mode, the strength and duration of the laser pulses are sufficient to ablate tissue at the area of tissue being treated to a controllable ablation depth and when in the coagulation mode, the strength and duration of the laser pulses are sufficient to generate a coagulation region having a controllable coagulation depth within the tissue remaining at the area of tissue being treated without ablating any tissue.

18. The medical laser delivery apparatus as claimed in claim 17 further comprising a graphical user interface through which a user selects the controllable ablation depth and the controllable coagulation depth.

19. The medical laser delivery apparatus as claimed in claim 18 wherein the laser delivery system comprises an articulated arm and one or more refocussing optics for refocussing the laser beam as its travels through the articulated arm.

20. The medical laser delivery apparatus as claimed in claim 19 wherein the laser delivery system further comprises a scanning handpiece at an end of the arm for providing the laser pulses to the area of tissue being treated.

21. The medical laser delivery apparatus as claimed in claim 20 wherein the refocussing optics are simple convex lenses.

22. The medical laser delivery apparatus as claimed in claim 21 wherein the laser source includes a laser having a short penetration depth.

23. The medical laser delivery apparatus as claimed in claim 22, wherein the first and second lasers are erbium lasers.

24. The medical laser delivery apparatus as claimed in claim 23 wherein the erbium lasers are Er:YAG lasers.

Claims 25-40 (Canceled)

41. A dual mode medical laser system, for sequentially ablating and coagulating a region of target tissue with ablation laser pulses followed by coagulation laser pulses, the dual mode medical laser system comprising:

a. a laser source comprising a first laser and a second laser for generating a first set of laser pulses and a second set of laser pulses at a wavelength;

b. means to combine pulses of the first set of laser pulses and the second set of laser pulses to provide a single laser output, the single laser output being capable of coagulating tissue with the system in a coagulation mode and ablating tissue with the system in an ablating mode; and

c. means to direct the single laser output to the region of the target tissue.

42. The dual mode medical laser system of claims 41 wherein the first laser and the second laser are Er:YAG lasers.

43. The dual mode medical laser system of claim 41 wherein the means to combine pulses of the first set of laser pulses and the second set of laser pulses is a galvanometer.

44. The dual mode medical laser system of claim 41 further comprising a user interface, wherein a user selects an ablation depth and a coagulation depth and wherein a series of the ablation laser pluses with a fluence corresponding to the selected ablation depth are generated followed by a series of the coagulation laser pulses with a fluence corresponding to the selected coagulation depth.

45. The dual mode medical laser system of claim 44 wherein the user interface comprises a mode selector for selecting between manual mode and scan mode, wherein the user further selects a scan size and a laser pulse pattern with the scan mode selected.

46. The dual mode medical laser system of claim 45 wherein the user interface is a graphical user interface for displaying the selected laser pulse pattern.

47. The dual mode medical laser system of claim 41 wherein the ablation laser pulses have a duration of approximately 500 microseconds and a fluence of approximately 2 Joules/cm^2.

48. The dual mode medical laser system of claim 41 wherein when the system is in the coagulation mode, the coagulation laser pulses of the first set of laser pulses and the second set of laser pulses each have a duration of approximately 150 microseconds and a combined fluence of approximately 200 milliJoules/cm^2.

49. The dual mode medical laser system of claim 41 wherein the means to direct the single laser output to the region of the target tissue comprises an articulated arm feature with a plurality of refocussing lenses for guiding and focussing the single laser output through the articulated arm feature.

50. A medical laser delivery apparatus for delivering a series of laser pulses having a wavelength, the medical laser delivery apparatus including non-ablative laser pulses for directing to an area of tissue to be treated and generating a region of coagulation to a controllable coagulation depth under a surface of the area of tissue, the apparatus comprising a laser source for generating the series of laser pulses including the non-ablative laser pulses to be delivered to the area of tissue to be treated in order to raise a temperature at the surface of the area of tissue to be treated to a temperature sufficient to generate coagulation at the coagulation depth when the laser source is in a coagulation mode, wherein the laser source comprises two or more lasers, the medical laser delivery apparatus further comprising a galvanometer that combines the series of laser pulses from

the two or more lasers into a single laser output by switching between laser outputs from the two or more lasers.

51. A medical laser comprising:

a. a laser source having two or more pulsed lasers for generating laser outputs having a wavelength, wherein a series of the pulses of laser light are combined into a single laser output by switching between the laser outputs with a galvanometer, the single laser output having a predetermined absorption, wherein the predetermined absorption forms a predetermined coagulation depth; and

b. a laser control system coupled to the laser source for controlling the laser source to deliver the laser output to a target area.

IX. EVIDENCE APPENDIX

Evidence Description:	Where Entered:
U.S. Pat. No. 5,662,643	Office Action mailed February 17, 2000
U.S. Pat. No. 5,098,426	Office Action mailed February 17, 2000
U.S. Pat. No. 4,672,969	Office Action mailed February 17, 2000
Selective Photothermolysis Anderson et al.	Office Action mailed February 17, 2000
U.S. Pat. No. 5,620,435	Office Action mailed February 17, 2000
U.S. Pat. No. 5,938,657	Office Action mailed February 17, 2000
Response filed May 17, 2000	Office Action mailed August 2, 2000
Office Action mailed August 2, 2000	Response filed October 2, 2000
Response filed October 2, 2000	Office Action mailed September 17, 2001
U.S. Patent No. 5,125,922	Office Action mailed September 17, 2001
Response mailed November 16, 2001	Advisory Action mailed February 14, 2002
RCE filed March 13, 2002	Office Action mailed May 28, 2002
Office Action mailed May 28, 2002	Response mailed September 30, 2002
Response mailed September 30, 2002	Office Action mailed December 26, 2002
Office Action mailed December 26, 2002	Response mailed April 28, 2003
Office Action mailed July 28, 2003	Response mailed November 28, 2003
Response mailed November 28, 2003	Office Action mailed May 14, 2004
Office Action mailed May 14, 2004	Response mailed July 14, 2004
Response mailed July 14, 2004	Advisory Action mailed April 17, 2005
RCE filed November 12, 2004 Office	Office Action mailed April 17, 2005
Office Action mailed April 7, 2005	Response mailed June 7, 2005
Response mailed June 7, 2005	Advisory Action mailed June 24, 2005

X. RELATED PROCEEDINGS APPENDIX

There are no related proceedings.

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SCIENCE

606/9

Selective Photothermolysis: Precise Microsurgery by Selective Absorption of Pulsed Radiation

R. Rox Anderson and John A. Parrish

Selective Photothermolysis: Precise Microsurgery by Selective Absorption of Pulsed Radiation

Abstract. *Suitably brief pulses of selectively absorbed optical radiation can cause selective damage to pigmented structures, cells, and organelles in vivo. Precise aiming is unnecessary in this unique form of radiation injury because inherent optical and thermal properties provide target selectivity. A simple, predictive model is presented. Selective damage to cutaneous microvessels and to melanosomes within melanocytes is shown after 577-nanometer (3×10^{-7} second) and 351-nanometer (2×10^{-8} second) pulses, respectively. Hemodynamic, histological, and ultrastructural responses are discussed.*

Many biomedical applications of lasers have been developed (*1*, *2*). The first effect of light on tissue is the absorption of photons, which leads either to photochemical reactions or to significant heating. With few exceptions (*3*), biomedical lasers use a variety of thermal effects (*4*). Rapid localized heating causes large thermal transients and shock waves which may propagate, causing mechanical damage. Many enzymes are heat-labile. Above 60° to 70°C, structural proteins including collagens are also denatured (*5*). Above 70° to 80°C, nucleic acids are denatured and membranes become permeable. Thus, essentially any mammalian tissue heated to 70° to 100°C may suffer protein denaturation, leading to "coagulation necrosis." Coagulation necrosis is useful for causing hemostasis due to the denaturation of plasma proteins and the closing of vessels. Above 100°C, vaporization of tissue water with rapid volume expansion followed by carbonization of the dry mass occurs. Rapid vaporization is useful for physically separating or ablating tissues.

Although the mode of damage is important, it is the spatial confinement of heating which mainly dictates which cells or tissues will be affected. Laser "microbeam" microsurgery has produced the most confined thermal damage in biology (*6*). Essentially any structure visualizable under light microscopy can serve as the target and can be selectively damaged. Although a powerful tool for the study of single cells or organelles in vitro, laser microbeams are impractical in cases where millions of cells are embedded in turbid, intact, living tissues. On this larger scale, thermal diffusion occurring during and after exposure and scattering and absorption of laser light within the tissue determine whether damage will be confined to the immediate path of a laser beam. Craters of coagulation necrosis with or without central vaporization have been described and modeled for a great variety of conditions (*7*). If the exposure time is prolonged, there is ample time during exposure for heat to diffuse to surrounding tissue and larger craters are seen. Scar formation is typical of such injuries.

We present here a simple scheme for confining thermally mediated radiation damage to chosen pigmented targets at the ultrastructural, cellular, or tissue structural levels. Experimental verification is shown for two biologically interesting targets—blood vessels and melanocytes. The confinement of damage can be as precise as with microbeam techniques, but millions of targeted structures are damaged simultaneously in vivo without precise aiming. This may be particularly useful in turbid tissues, which unlike the eye, limit the precision with which isolated structures can be exposed. Tissues between targeted structures, including overlying or immediately neighboring cells, are spared, potentially reducing widespread destruction and nonspecific fibrosis. There appear to be few fundamental limitations to applying the approach in various tissues and to a wide range of targets. We call the technique selective photothermolysis (SP).

This technique relies on selective absorption of a brief radiation pulse to generate and confine heat at certain pigmented targets. An absolute requirement is that the targets have greater optical absorption at some wavelength than their surrounding tissues. This requirement can be met either by choosing endogenously pigmented targets, as we do here, or by using staining or dye-labeling techniques. During laser exposure, absorption and radiationless deexcitation convert radiant energy into heat within each target in the exposure field. The targets begin to transfer this heat to their cooler surroundings mainly by thermal diffusion, but this process takes some time and heat is initially confined

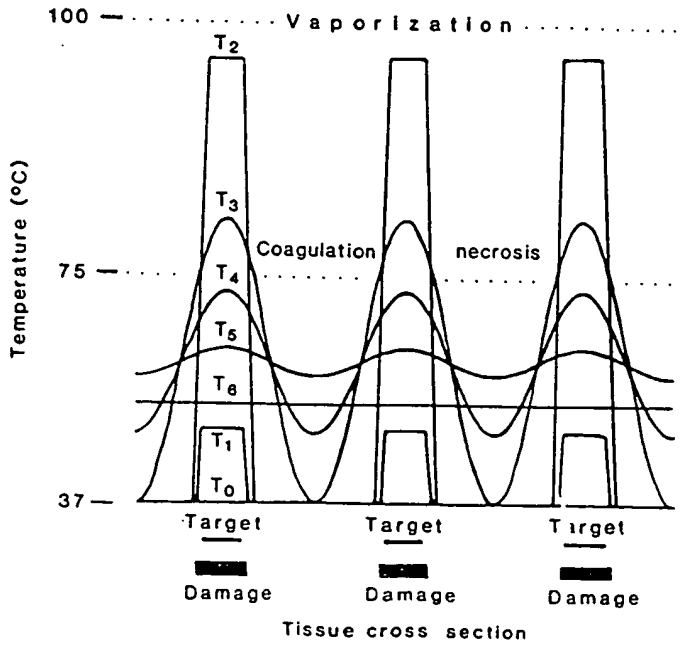

Fig. 1. Schematic temperature profiles during selective photothermolysis: T_0, before laser exposure (uniform body temperature); T_1, during laser exposure (selective rapid target heating); T_2, at the end of laser exposure (targets irreversibly damaged); T_3, one thermal relaxation time after laser pulse (targets cooling, surrounding tissue warming); T_4, two thermal relaxation times after laser pulse; T_5, five thermal relaxation times after laser pulse; and T_6, tissue slowly returing to ambient thermal equilibrium.

to the targets during exposu[illegible]. At the end of an appropriately brief laser exposure, the temperature of the target may easily have surpassed that required for thermal denaturation while that of the surrounding tissue remains well below this temperature. Immediately after the exposure, thermal diffusion cools the targets and warms the tissue between them but not necessarily to denaturing temperatures. The warmed tissue, with its specifically denatured or otherwise thermally damaged targets, then slowly cools. The sequence of thermal profiles during SP is depicted schematically in Fig. 1.

The primary concern in choosing the laser wavelength for SP is to maximize selective optical absorption in the desired targets. The fraction of energy incident on a target that is absorbed in a single pass through it is roughly

$$A \cong 1 - e^{-\alpha d} \cong 1 - 10^{-\epsilon c d}$$

where α is an absorption coefficient for the target, ϵ is the molar extinction coefficient of the major target chromophore, c is its concentration, and d is an average target size; $\alpha \cong 2.3\ \epsilon c$. Deviations from this relation can occur in highly turbid tissues; A cannot exceed 1.0. For $\epsilon c d \geq 1$, $A \geq 0.9$; hence, there is little to be gained per se from choosing wavelengths or conditions at which $\epsilon c d$ greatly exceeds unity. This fortunately allows some apparently minor target absorption bands to be useful for SP. As the value of αd approaches or exceeds 1.0, the interior of the target is shielded from radiation and hence most of the heat is generated at the periphery of each target. At such a point in tissue, the rate of energy absorbed per unit volume is $(\delta E/\delta t) = I\alpha$, where I is the radiation intensity at the site in question. If most of the absorbed energy is dissipated as heat, the ratio of heat input at the boundary of a target to that of its surroundings is simply the ratio of the α values. For excellent specificity in heating targets, the ratio $(\alpha_{target}/\alpha_{tissue})$ should be on the order of 10 or greater, but SP may be achievable with ratios as low as 2.

The wavelength chosen also determines the tissue depths at which SP can occur. Both optical scattering and absorption impede radiation. Scattering by connective tissue varies inversely with optical wavelength, and major tissue chromophores tend to have greater absorption at shorter wavelength (*8*, *9*). Thus, in general, SP is possible at greater tissue depths with longer optical wavelengths, until the near-infrared absorption bands of water near 2000 nm are reached. If the targets lie beneath or within a pigmented tissue layer, a wavelength must be chosen to be poorly absorbed by the competing pigment but relatively well absorbed by the targets themselves. This is the case for cutaneous microvessels, which lie beneath the melanin-containing epidermis.

If specific stains or dyes are used to label targets for SP, a wavelength poorly absorbed by the unstained tissue must be chosen. An "optical window" exists for most soft tissues in the red and near-infrared regions, with $\alpha_{tissue} \cong 5\ cm^{-1}$ at 650 to 850 nm (*9*). Thus, a typical blue (red-absorbing) dye with $\epsilon \cong 10^5$ liter mole^{-1} cm^{-1} would require a concentration of about 50 μM in the targets for $\alpha_{target} \cong 10\ cm^{-1}$, that is, for SP to be possible. Dyes have been used to enhance laser-induced damage (*1–3*, *6*, *10*), but in most studies either photochemical or poorly confined thermal mechanisms account for the responses noted. Apparently dye-labeled antibody targeting of laser damage has not been attempted.

No matter how judiciously one has chosen the laser wavelength, poorly confined damage will result if the exposure duration is too long. During long exposures, heat transfer occurs and the entire tissue is heated relatively uniformly, causing nonspecific coagulation necrosis even though specific pigments are the sites of optical absorption. If, in the other extreme, an instantaneous laser pulse is delivered, extreme temperature differences between a target and its surroundings can be achieved, which might cause vaporization and shock wave damage. Between these two extremes of exposure duration, an interesting continuum with varying degrees of confinement of the thermal damage exists. The transition from specific to nonspecific thermal damage occurs as the laser exposure duration (pulse width) equals and then exceeds the thermal relaxation time (t_r) for the targets. For spheres of diameter d, $t_r \cong (d^2/27\kappa)$, and for long cylinders, $t_r \cong (d^2/16\kappa)$, where t_r is defined as the time required for the central temperature of a gaussian temperature distribution with a width equal to the target's diameter to decrease by 50 percent. For a

Table 1. Data on targets (microvessels and melanosomes) used for selective photothermolysis.

Target	d (μm)	t_r (sec)	Depth in tissue (μm)	Major pigment	c (M)	Absorption spectrum (*9*)
Microvessels	10 to 50, cylindrical	4.8×10^{-5}	150 to 400 (superficial plexus)	Oxyhemoglobin	2.3×10^{-3} (average whole blood)	Maxima at 418, 542, 577 nm
Melanosomes	0.5 to 1.0, ellipsoid	5×10^{-8}	50 to 150 (stratum basali of epidermis)	Melanin	?	Broad absorption at 200 to 1200 nm; decreases with wavelength

Table 2. Target optical data, and estimation of laser exposure dose D_0 for selective photothermolysis (SP).

Major target pigment	Wavelength (nm)	ϵ (liter mole^{-1} cm^{-1})	ϵc (cm^{-1})	$\epsilon c d$*	α_{target} (cm^{-1})	α_{tissue} (cm^{-1})	$\frac{\alpha_{target}}{\alpha_{tissue}}$	f (*8*,*9*)	Estimated D_0 for SP of target (J cm^{-2})
				Microvessels					
HbO_2	418	5.24×10^5	1200	2.4	2760	~ 30	92	~ 0.1	0.6
	577	6.08×10^4	140	0.28	322	~ 8	40	~ 0.5	1.1
				Melanosomes					
Melanin	351	?	~ 10^4	~ 1	~ 2×10^4	~ 80	~ 250	~ 0.5	0.016
	700	?	~ 10^3	~ 0.1	~ 2×10^3	~ 5	~ 400	~ 0.8	0.1*

*d = 20 μm for microvessels and 1 μm for melanosomes.

thermal diffusivity (κ) of 1.3 × [illegible] cm^2 sec^{-1} for both target and surroundings, t_r for spherical targets with diameters of 0.1, 1.0, 10, 100, and 1000 μm has the values 3×10^{-9}, 3×10^{-7}, 3×10^{-5}, 3×10^{-3}, and 3×10^{-1} second, respectively. Thus, SP requires nanosecond-domain or shorter pulses on the subcellular organelle scale, microsecond-domain or shorter pulses on the cell-specific scale, and millisecond-domain or shorter pulses for noncapillary vessels and other small structures. Because of the greater relative heat losses from smaller targets during exposures, it is possible that small targets with t_r smaller than a carefully chosen pulse width would be spared from damage, whereas larger but otherwise similar targets would undergo SP during the same exposure.

If the laser pulse width is suitably brief, thermal diffusion during exposure can be neglected and the incident laser exposure dose required for SP can be easily estimated. The temperature rise (ΔT) of any target volume element is then

$$\Delta T = \Delta E/\rho S$$

where ΔE is the energy input per unit volume, S is the specific heat (≅ 4.2 J g^{-1} $°C^{-1}$) and ρ is the density (≅ 1.1 g cm^{-3}). In most mammalian tissues, $\Delta T \geq 40°C$ should correspond to significant thermal damage. For a target with $\alpha d < 1$,

$$\Delta E \cong f D_0 \alpha$$

where D_0 is the laser exposure dose (in joules per square centimeter) incident on the tissue, and the incident intensity is decreased by a factor f before reaching the targets. Hence the exposure dose necessary for SP is

$$D_0 \cong \frac{\rho S \Delta T}{f\alpha}, \quad \alpha d < 1$$

No correction has been made for the attenuation of radiation within the targets. For cases where $\alpha d > 1$, one can estimate D_0 by assuming that all the energy incident on the cross sectional area of target is absorbed and distributed over the target's volume, giving

$$D_0 \cong \frac{\rho S \Delta T A_t}{f V_t}, \quad \alpha d > 1$$

where A_t is the target area and V_t is the target volume. Because SP invests energy in heating only small targets and not the entire tissue mass, as the pulse width is decreased sufficiently to cause SP one would expect the incident energy necessary for a biologic effect to decrease also. Similar reasoning was invoked by Hayes and Wolbarsht (*11*) to explain the lower retinal damage threshold seen after 30-nsec (0.07 J cm^{-2}) versus 250-μsec (0.7 J cm^{-2}) 694-nm ruby laser pulses (*12*). Damage at the shorter pulse width may have been due to vaporization of melanosomes within the retinal pigment epithelium, whereas the results with the longer pulse width were attributed to the heating of larger volumes of tissue.

Fig. 2. Transmission electron micrograph (×9,300) of cutaneous melanocyte after in vivo irradiation with 351-nm excimer laser pulse, showing specific disruption of melanosomes (arrows) (inset, ×32,000). *Nu*, nucleus.

We first studied SP of cutaneous microvasculature to develop a specific therapy for hemangiomas (*13*). Tables 1 and 2 give pertinent data for SP of microvessels. Radiation at the 577-nm oxyhemoglobin (HbO_2) absorption band was chosen because this wavelength penetrates skin well (*8*, *9*), minimizes absorption by melanin in the overlying epidermis (*9*, *13*), and offers excellent selective absorption by blood vessels. For vessels 20 μm in diameter, t_r is about 50 μsec. A dye laser with 0.3-μsec pulse width (Candela model SLL-1100) was used to irradiate uniform 3-mm sites with single pulses ranging from 0.5 to 5 J cm^{-2} on the forearms of eight fair-skinned volunteers. Responses were observed clinically and histologically immediately, 24, and 48 hours after exposure.

Striking vascular changes were noted with little or no damage to the overlying epidermis or structures between vessels. A D_0 of 1.5 to 2 J cm^{-2} consistently produced a pinprick sensation and within a minute the forearm turned purple (purpura), indicating superficial hemorrhage. Twenty-four hours after exposure, a necrotizing vasculitis without epidermal changes was seen histologically. The purpura was an all-or-none response with a threshold of 1.27 ± 0.18 J cm^{-2}. Cooling the skin to 10°C produced a consistent increase in this threshold dose to 1.60 ± 0.11 J cm^{-2} ($P < .05$ by paired t-test), supporting a peak temperature-dependent damage mechanism. The magnitude of this temperature effect is most consistent with microvaporization as the cause for the microhemorrhage leading to purpura.

Hamster cheek pouches were exposed to the same 577-nm dye laser in vivo; this procedure allowed the direct visualization of microvessels. With increasing dose from 0.5 to 2.0 J cm^{-2}, we observed (i) immediate brown discoloration of blood; (ii) a sudden, viscous, decrease in blood flow; (iii) permanent hemostasis (> 15 minutes); and (iv) vessel rupture with hemorrhage. This progression of effects is presumably related to the increasing target temperatures achieved, with the first three effects due to hemoglobin, plasma, and tissue protein denaturations, respectively, whereas the fourth effect may be due to vaporization or shock wave damage.

We also studied SP of cutaneous melanosomes (1-μm pigment granules) and melanin-containing cells (Tables 1 and 2). In the deeply penetrating spectral region around 700 nm, absorption by blood is minimal but melanin has considerable absorption (*9*). We chose a 351-nm XeF excimer laser (Tachisto model 400 XR), however, to maximize absorption by melanized targets at a wavelength that penetrates poorly beyond the epidermal basal cell layer. For 1-μm melanosome-specific photothermolysis, a pulse width of less than 50 nsec is necessary; the excimer laser pulse width was 20 nsec.

Light microscopy of exposure sites 2 mm by 10 mm in six Caucasian subjects biopsied 24 hours after receiving single pulses of excimer laser exposure doses between 0.05 and 0.40 J cm^{-2} revealed highly specific damage to melanin-containing cells. Transmission electron microscopy of representative biopsies showed degenerative changes selectively involving isolated melanocytes and melanin-containing keratinocytes in the basal cell layer after doses of 0.1 to 0.2 J cm^{-2}. Nearly 100 percent of the pigmented basal cells were necrotic after exposures of 0.2 to 0.4 J cm^{-2}, but the less pigmented and immediately neighboring suprabasal keratinocytes were strikingly less affected or normal. There

was no evidence of deep follicular vascular damage. Electron microscopy showed enlarged, focally disrupted, and centrally electron-lucent melanosomes within affected melanocytes and basal keratinocytes (Fig. 2), whereas organelles of adjacent nonpigmented cells (for example, Langerhans cells) were unaltered. Biopsies taken immediately after exposure disclosed similar changes occurring selectively in melanosomes; these results suggest that these melanin-containing organelles are the primary sites of injury. Grossly acute inflammation for several days was followed by hypopigmentation developing 7 to 10 days after exposure, without gross epidermal sloughing. Exposed sites then gradually repigmented without apparent scarring.

The feasibility of vascular, cellular, and ultrastructurally specific SP is apparent from this work. Whatever usefulness SP of vascular or pigment cell targets may have, the general technique may find many biomedical applications. As a microsurgical technique, cell-specific SP affects large cell numbers without widespread tissue damage. In tissues such as the central nervous system where surgery is hazardous and single cells are the functional operating units, SP may be especially valuable. If tunable lasers and cell-specific dye delivery systems can be used, choice among many targets is possible. The biologic repair of such highly specific damage needs to be understood.

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14. We thank H. Furumoto, T. Harrist, W. Gange, P. Paul, and P. Mock for invaluable contributions. G. F. Murphy provided the ultrastructural observations. Supported by NIH grant R01025395 and the Arthur O. and Gullan M. Wellman Foundation.

24 August 1982; revised 20 December 1982

FORM PTO-1449
(Modified)

U.S. Department of Commerce
Patent and Trademark Office

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Use Several Sheets If Necessary)

(37 CFR § 1.98(b))

Attorney Docket No.: SCI-00100	Serial No.: 09/018,104
Applicant: James L. Hobart *et al.*	
Filing Date: February 3, 1998	Group Art Unit: 3739

U.S. PATENT DOCUMENTS

Examiner Initials		Serial / Patent Number	Issue Date	Applicant / Patentee	Class	Subclass	Filing Date
	AA	3,466,111	9/9/69	D.H. Ring	~~350~~	~~54~~	12/29/66
	AB	4,473,074	9/25/84	Vassiliadis	~~128~~	~~303.1~~	9/28/81
	AC	4,963,143	10/16/90	Pinnow	~~604~~	14	4/3/89
	AD	5,098,426	3/24/92	Sklar et al.	~~606~~	~~14~~	2/6/89
	AE	5,312,398	5/17/94	Hobart et al.	~~606~~	~~14~~	4/13/92
	AF	5,531,740	7/2/96	Black	~~606~~	~~9~~	9/6/94
	AG	5,540,676	7/30/96	Freiberg	~~606~~	~~5~~	4/14/95
	AH	5,618,285	4/8/97	Zair	~~606~~	10	2/2/95
	AI	5,662,644	9/2/97	Swor	~~606~~	~~9~~	5/14/96
	AJ						

FOREIGN PATENTS OR PUBLISHED FOREIGN PATENT APPLICATIONS

		Document Number	Publication Date	Country / Patent Office	Class	Subclass	Translation	
							Yes	No
	AK	0 164 751 A2	12/18/85	EP	H 01	3/097	N/A	
	AL	EP 0 755 698 A2	1/29/97	EP	A61N	5/06	N/A	
	AM	DE 195 21 003 C1	6/96	DE	A 61 B	17/36		✓
	AN	WO 92/18057	10/29/92	PCT	A61B	17/22	~~N/A~~	✓
	AO							

OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)

	AP	
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Examiner: _____ Date Considered: January 21, 2000

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

PATENT
Attorney Docket No.: SCI-00100

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Group Art Unit: 3739
James L. Hobart et al.	Examiner: Shay, D.
Serial No.: 09/018,104	
Filed: February 3, 1998	**RESPONSE TO OFFICE ACTION MAILED February 17, 2000**
For: **DUAL MODE LASER DELIVERY SYSTEM PROVIDING CONTROLLABLE DEPTH OF TISSUE ABLATION AND CORRESPONDING CONTROLLABLE DEPTH OF COAGULATION**	260 Sheridan Avenue, Suite 420 Palo Alto, California 94306 (650)833-0160

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir/Madam:

AMENDMENT

In the Claims

Please amend the claims as follows:

1. (Amended) A medical laser delivery apparatus for delivering one or more pulses to an area of tissue to be treated and generating a region of coagulation to a controllable coagulation depth under a surface of the area of tissue comprising a laser source

CERTIFICATE OF MAILING (37 CFR § 1.8(a))

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the U.S. Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the: Assistant Commissioner for Patents, Washington D.C 20231

HAVERSTOCK & OWENS LLP

Date: 5/17/00 By: [signature]

for generating a series of one or more non-ablative pulses to be delivered to the area of tissue to be treated in order to raise a temperature at the surface of the area of tissue to be treated to a temperature sufficient to generate coagulation at the coagulation depth when the laser source is in a coagulation mode, wherein the laser source comprises two or more lasers which are combined into a single laser output to provide the one or more non-ablative pulses.

8. (Amended) The medical laser delivery apparatus as claimed in claim 1 wherein [the] at least one of the lasers [source includes a laser having] has a short penetration depth.

9. (Amended) The medical laser delivery apparatus as claimed in claim 8 wherein [the] at least one of the lasers is an erbium laser.

10. (Amended) The medical laser delivery apparatus as claimed in claim 8 wherein the erbium laser is an Er:YAG laser.

11. (Amended) A medical laser comprising:

a. a laser source having two or more lasers which are combined for generating a laser beam having a predetermined absorption length, wherein the absorption length forms a predetermined coagulation depth in response to an ablative laser pulse; and

b. a laser control system coupled for controlling the laser source for generating a plurality of coagulative laser pulses, such that each such coagulative laser pulse is delivered in sequence to a target area to form a coagulation region deeper than the predetermined coagulation depth.

17. (Amended) A medical laser delivery apparatus for treating an area of tissue comprising:

a. a laser source having two or more lasers which are combined into a single laser output by a combining apparatus for generating a series of one or more laser pulses each having a strength and a duration;

b. a laser delivery system coupled to the laser source for delivering the laser pulses from the laser source to the area of tissue being treated;

c. a control system coupled to the laser source for controlling generation of the laser pulses from the laser source, wherein the laser source operates in both an ablation mode and a coagulation mode such that when in the ablation mode, the strength and duration of the laser pulses are sufficient to ablate tissue at the area of tissue being treated to a controllable ablation depth and when in the coagulation mode, the strength and duration of the laser pulses are sufficient to generate a coagulation region having a controllable coagulation depth within the tissue remaining at the area of tissue being treated without ablating any tissue.

23. (Amended) The medical laser delivery apparatus as claimed in claim 22 wherein at least one of the lasers is an erbium laser.

24. (Amended) The medical laser delivery apparatus as claimed in claim 22 wherein the erbium laser is an Er:YAG laser.

REMARKS

Applicants respectfully request further examination and reconsideration in view of the above amendment and the remarks set forth below. Prior to this amendment, Claims 1-14 and 17-24 were pending. Claims 15, 16 and 25-40 have previously been withdrawn in

response to the Examiner's Restriction Requirement. By the above amendment, Claims 1, 8-11, 17, 23 and 24 have been amended. Accordingly, Claims 1-14 and 17-24 are still pending.

Rejections Under 35 U.S.C. § 112

Within the Office Action, Claims 1-14 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. The applicants respectfully traverse this rejection. Regarding Claims 1 and 2, it is stated within the Office Action that Claim 1 is incomplete in view of the recitation in Claim 2. Claim 1 is directed to a medical laser delivery apparatus for delivering one or more pulses to an area of tissue to be treated. Claim 2 adds a further limitation to the medical laser delivery apparatus of Claim 1, specifying that the medical laser delivery apparatus further comprises a laser delivery system coupled to the laser source for delivering the one or more pulses from the laser source to the area of tissue to be treated. As specified in these claims, the overall apparatus is a medical laser delivery apparatus. Claim 2 adds the further limitation that the medical laser delivery apparatus includes a laser delivery system coupled to the laser source for delivering the one or more pulses from the laser source to the area of tissue to be treated. Claim 3 further specifies that the laser delivery system comprises an articulated arm and one or more refocussing optics for refocussing the laser pulses as they travel through the arm. Accordingly, Claims 1 and 2 do particularly point out and distinctly claim the subject matter which applicants regard as the invention.

Within the Office Action, it is further stated that in Claim 11 there is no antecedent basis in the specification for generating a coagulation depth in response to an ablative pulse. The applicants also respectfully traverse this rejection. Within the specification it is stated that "an ablation pulse from an erbium laser will create a coagulation region having a thickness of approximately 10 microns." [Specification, p. 6, lines 15-16] Accordingly, there is a clear antecedent within the specification of the present invention for this limitation. The Examiner is therefore requested to withdraw the rejections under 35 U.S.C. § 112.

Rejections Under 35 U.S.C. § 102

Within the Office Action, Claims 1, 2, 8 and 11 have been rejected under 35 U.S.C. § 102(e) as being clearly anticipated by U.S. Patent No. 5,662,643 to Kung et al. (hereinafter "Kung"). Kung teaches a laser welding system for surgically bonding tissue together. The surgical system of Kung includes a system input 10, a laser source 20, a delivery system 40 and a temperature feedback loop 30. [Kung, col. 2, lines 46-51] The system of Kung provides a coherent beam of light at a predetermined wavelength corresponding to a specific thickness of tissue at which substantially full absorption of the laser energy occurs, without allowing the temperature anywhere in the subject tissue to exceed a predetermined tissue temperature. [Kung, col. 2, lines 9-16] Kung does not teach a laser source which comprises two or more lasers which are combined into a single laser output to provide one or more non-ablative pulses.

In contrast to the teachings of Kung, the dual mode laser delivery system of the present invention includes a laser source with a short penetration depth and two or more lasers which are combined into a single laser output. A controllable ablation depth is achieved by the laser delivery system of the present invention by providing an appropriate series of pulses from the laser source having an energy and exposure time to achieve ablation of the exposed area of skin to the desired depth. Once ablation of the skin has been performed, a coagulation region to the desired coagulation depth is then generated within the remaining exposed layer of skin by preferably applying a series of one or more very short non-ablative laser pulses from the laser source at a high repetition rate in order to raise the temperature of the surface of the skin to a desired temperature for a period of time. The order of delivery of the ablation sequence and the coagulation sequence can also be reversed from that described if desired.

The laser source of the present invention includes two lasers 32 and 34 which generate laser beams 33 and 35, as illustrated in Figure 3. The two laser beams 33 and 35 are combined into a single laser output 37 by the galvonometer 36 which switches between the two laser outputs 33 and 35. The galvonometer 36 then provides the laser output 37 from the

laser source 31. As discussed above, Kung does not teach a laser source which comprises two or more lasers which are combined into a single laser output.

The independent Claim 1 is directed to a medical laser delivery apparatus for delivering one or more pulses to an area of tissue to be treated and generating a region of coagulation to a controllable coagulation depth under a surface of the area of tissue. The apparatus of Claim 1 comprises a laser source for generating a series of one or more non-ablative pulses to be delivered to the area of tissue to be treated in order to raise a temperature at the surface of the area of tissue to be treated to a temperature sufficient to generate coagulation at the coagulation depth when the laser source is in a coagulation mode. Claim 1 includes the further limitation that the laser source comprises two or more lasers which are combined into a single laser output to provide the one or more non-ablative pulses. As discussed above, Kung does not teach a laser source which comprises two or more lasers which are combined into a single laser output to provide the one or more non-ablative pulses. For at least these reasons, the independent Claim 1 is therefore allowable over the teachings of Kung.

Claims 2 and 8 are both dependent on the independent Claim 1. As described above, the independent Claim 1 is allowable over the teachings of Kung. Accordingly, Claims 2 and 8 are both also allowable as being dependent upon an allowable base claim.

The independent Claim 11 is directed to a medical laser comprising a laser source and a laser control system. Claim 11 specifies that the laser source has two or more lasers which are combined for generating a laser beam having a predetermined absorption length, wherein the absorption length forms a predetermined coagulation depth in response to an ablative laser pulse. As discussed above, Kung does not teach a laser source which comprises two or more lasers which are combined for generating a laser beam. For at least these reasons, the independent Claim 11 is therefore allowable over the teachings of Kung.

Rejections Under 35 U.S.C. § 103

Within the Office Action, Claims 3, 6-8, 11-14 and 17-19 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,098,426 to Sklar et al. (hereinafter "Sklar") in combination with U.S. Patent No. 4,672,969 to Dew (hereinafter "Dew"), U.S. Patent No. 5,620,435 to Belkin et al. (hereinafter "Belkin") and the article entitled "Selective Photothermolysis: Precise Microsurgery by Selective Absorption of Pulsed Radiation" by R. Rox Anderson and John A. Parrish (hereinafter "Anderson"). Sklar teaches a method and apparatus for precision laser surgery. Sklar teaches a system which includes an imaging system providing a surgeon with abundant visual information on a video screen with indication of precisely where, a focused surgical laser beam is directed. [Sklar, Abstract] Sklar does not teach a medical laser with a laser source with two or more lasers which are combined for generating a laser beam and a laser control system coupled for controlling the laser source for generating a plurality of coagulative laser pulses.

Dew teaches a laser healing method to effect wound closure and reconstruction of biological tissue. Optical energy is applied to produce thermal heating of biological tissue to a degree suitable for denaturing the tissue proteins such that the collagenous elements of the tissue form a biological glue to seal and reconstruct the tissue being heated. [Dew, Abstract] The system of Dew includes a laser 20. Dew teaches a marker laser 30 which is coaligned with the infrared beam of the laser 20. Further, Dew teaches that an auxiliary source of optical energy 50 can be incorporated into the apparatus to emit radiation having a wavelength which is intensely absorbed by biological tissue. Dew does not teach a medical laser with a laser source with two or more lasers which are combined for generating a laser beam and a laser control system coupled for controlling the laser source for generating a plurality of coagulative laser pulses.

Belkin teaches a method for welding ocular tissues to each other using a carbon dioxide laser. [Belkin, col. 2, lines 35-44] Belkin does not teach a medical laser with a laser source with two or more lasers which are combined for generating a laser beam and a laser

control system coupled for controlling the laser source for generating a plurality of coagulative laser pulses.

Anderson teaches a scheme for confining thermally mediated radiation damage to chosen pigmented targets. [Anderson, p. 524] The technique relies on selective absorption of a brief radiation pulse to generate and confine heat at certain pigmented targets. [Anderson, p. 524] Anderson does not teach a medical laser with a laser source with two or more lasers which are combined for generating a laser beam and a laser control system coupled for controlling the laser source for generating a plurality of coagulative laser pulses.

Accordingly, neither Sklar, Dew, Belkin, Anderson nor their combination teach a medical laser with a laser source with two or more lasers which are combined for generating a laser beam and a laser control system coupled for controlling the laser source for generating a plurality of coagulative laser pulses.

Claims 3 and 6-8 are all dependent on the independent Claim 1. As described above, the independent Claim 1 is allowable over the teachings of Kung. Accordingly, Claims 3 and 6-8 are all also allowable as being dependent upon an allowable base claim.

The independent Claim 11 is directed to a medical laser comprising a laser source and a laser control system. Claim 11 specifies that the laser source has two or more lasers which are combined for generating a laser beam having a predetermined absorption length, wherein the absorption length forms a predetermined coagulation depth in response to an ablative laser pulse. The laser control system of Claim 11 is coupled for controlling the laser source for generating a plurality of coagulative laser pulses, such that each such coagulative laser pulse is delivered in sequence to a target area to form a coagulation region deeper than the predetermined coagulation depth. As discussed above, neither Sklar, Dew, Belkin, Anderson nor their combination teach a medical laser with a laser source with two or more lasers which are combined for generating a laser beam and a laser control system coupled for controlling the laser source for generating a plurality of coagulative laser pulses. For at least these reasons, the independent Claim 11 is therefore allowable over the teachings of Sklar, Dew, Belkin, Anderson and their combination.

Claims 12-14 are all dependent on the independent Claim 11. As described above, the independent Claim 11 is allowable over the teachings of Kung and also the teachings of Sklar, Dew, Belkin, Anderson and their combination. Accordingly, Claims 12-14 are all also allowable as being dependent upon an allowable base claim.

The independent Claim 17 is directed to a medical laser delivery apparatus for treating an area of tissue which comprises a laser source, a laser delivery system and a control system. Claim 17 specifies that the laser source has two or more lasers which are combined into a single laser output by a combining apparatus for generating a series of one or more laser pulses each having a strength and a duration. Claim 17 further specifies that the control system is coupled to the laser source for controlling generation of the laser pulses from the laser source, wherein the laser source operates in both an ablation mode and a coagulation mode such that when in the ablation mode, the strength and duration of the laser pulses are sufficient to ablate tissue at the area of tissue being treated to a controllable ablation depth and when in the coagulation mode, the strength and duration of the laser pulses are sufficient to generate a coagulation region having a controllable coagulation depth within the tissue remaining at the area of tissue being treated without ablating any tissue. As discussed above, neither Sklar, Dew, Belkin, Anderson nor their combination teach a medical laser with a laser source with two or more lasers which are combined for into a single laser and a control system coupled for controlling the laser source for generating a plurality of coagulative laser pulses. For at least these reasons, the independent Claim 17 is therefore allowable over the teachings of Sklar, Dew, Belkin, Anderson and their combination.

Claims 18 and 19 are both dependent on the independent Claim 17. As described above, the independent Claim 17 is allowable over the teachings of Sklar, Dew, Belkin, Anderson and their combination. Accordingly, Claims 18 and 19 are both also allowable as being dependent upon an allowable base claim.

Within the Office Action, Claims 4, 5, 9, 10 and 20-24 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Sklar in combination with Dew, Anderson, Belkin and further in view of U.S. Patent No. 5,938,657 to Assa et al. (hereinafter "Assa"). Assa

teaches an apparatus for delivering energy within continuous outline. Claims 4, 5, 9 and 10 are all dependent on the independent Claim 1. As described above, the independent Claim 1 is allowable over the teachings of Kung and the teachings of Sklar, Dew, Belkin, Anderson and their combination. Accordingly, Claims 4, 5, 9 and 10 are all also allowable as being dependent upon an allowable base claim.

Claims 20-24 are all dependent on the independent Claim 17. As described above, the independent Claim 17 is allowable over the teachings of Sklar, Dew, Belkin, Anderson and their combination. Accordingly, Claims 20-24 are all also allowable as being dependent upon an allowable base claim.

For the reasons given above, Applicants respectfully submit that the claims are in a condition for allowance, and allowance at an early date would be appreciated. Should the Examiner have any questions or comments, they are encouraged to call the undersigned at (650) 833-0160 to discuss the same so that any outstanding issues can be expeditiously resolved.

Respectfully submitted,
HAVERSTOCK & OWENS LLP

Dated: May 17, 2000

By: Jonathan O. Owens
Jonathan O. Owens
Reg. No.: 37,902

Attorneys for Applicant

UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/018,104	02/03/98	HOBART J	PHAN-00100

QM32/0217

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
3739	

DATE MAILED: 02/17/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/648,104	Holmes
Examiner	**Group Art Unit**
J. Shay	3739

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on November 12, 1999.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1-40 is/are pending in the application.

Of the above claim(s) 15, 16 + 25-40 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-14 + 17-24 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Action Summary

Claims 13, 16 and 25-40 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention. Election was made **without** traverse in Paper No. 7.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 exactly what is to be encompassed by the term "laser dilvery opparatus" in view of the recitation in claim 2 and the extent that claim 2 limits claim 1, claim 1 is incomplete. Claim 2 is indefinite as it fails to further limit claim 1. In claim 11 there is no antecedent basis in the originally filed specification for generating a coagulation depth in response to an ablative pulse.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1, 2, 8 and 11 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Kung et al.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3, 6-8, 11-14, and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sklar et al in combination with Dew ('969), Belkin et al and Anderson et al.. Sklar et al teach a laser system with a graphical interface and teach that it can be used for any type of surgery and with any type of laser and that the depth of the laser action can be input and displayed. Dew (969) teaches the use of a carbon dioxide laser as a cutting laser and teaches that the power of a pulse determines the amount of heat deposited in the tissue, Balkin et al teaches that carbon dioxide lasers can be used to heat, rather than cut tissue. Anderson teach the way parameters such as absorptivevity, ~~sport~~ spot size, and pulse width interrelate to control the amount of energy absorbed by tissue. It would have been obvious to the artisan of ordinary skill to use a carbon dioxide laser as taught by Dew ('696) in the graphical user interface of Sklar et al, since this is to be used with any laser, as taught by Sklar et al, to also configure the laser to coagulate as taught by Belkin et al, since this would render the device more versital, at no extra cost, and is within the scope of one having ordinary skill in the art to shown by Anderson et al, and employ

an articulated arm with refocussing optics, since these are notorious in the art for transporting infrared radiation such as that from Carbon dioxide lasers, official notice of which is hereby taken, thus producing a device such as claimed.

Claims 4, 5, 9, 10, and 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sklar et al in combination with Dew ('969), Anderson et al and Belkin et al as applied to claims 3, 6-8, 12-14 and 17-19 above, and further in view of Assa et al..

Assa et al teach a scanning handpiece and the equivalence of carbon dioxide and Erbium YAG lasers. Thus it would have been obvious to the artisan of ordinary skill to employ a handpiece as taught by Assa et al, since this allows more consistency of treatment and to employ an erbuim laser, since thse are equivalent to the carbon dioxide laser, thus producing a device such as claimed.

Any inquiry concerning this communication should be directed to David Shay at telephone number (703) 308-2215.

David Shay:bhw
February 4, 2000

DAVID M. SHAY
PRIMARY EXAMINER
GROUP 3700

FORM PTO-892 (REV. 2-92) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

SERIAL NO.	GROUP ART UNIT	ATTACHMENT TO PAPER NUMBER
09/018,104	3739	9

NOTICE OF REFERENCES CITED

APPLICANT(S): Hobart et al

U.S. PATENT DOCUMENTS

*		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE IF APPROPRIATE
	A	4672964	6/16/87	Dew	606	3	
	B	5620435	4/15/97	Bolton et al	606	4	
	C	5662643	9/2/97	Kung et al	606	9	
	D	5938657	8/17/99	Issa et al	606	9	
	E						
	F						
	G						
	H						
	I						
	J						
	K						

FOREIGN PATENT DOCUMENTS

*		DOCUMENT NO.	DATE	COUNTRY	NAME	CLASS	SUB-CLASS	PERTINENT SHTS. DWG	PERTINENT PP. SPEC.
	L								
	M								
	N								
	O								
	P								
	Q								

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

R	"Selective Photothermolysis: Precise Microsurgery by Selective Absorption of Pulsed Radiation" by Anderson et al, Science, Vol 220, 4/1983, pp 524-527
S	
T	

FORM PTO-1449 (Modified)

U.S. Department of Commerce Patent and Trademark Office

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Use Several Sheets If Necessary)

(37 CFR § 1.98(b))

Attorney Docket No.: SCI-00100	Serial No.: 09/018,104
Applicant: James L. Hobart *et al.*	
Filing Date: February 3, 1998	Group Art Unit: 3739

U.S. PATENT DOCUMENTS

Examiner Initials		Serial / Patent Number	Issue Date	Applicant / Patentee	Class	Subclass	Filing Date
	AA	3,466,111	9/9/69	D.H. Ring	~~350~~	~~54~~	12/29/66
	AB	4,473,074	9/25/84	Vassiliadis	~~128~~	~~303.1~~	9/28/81
	AC	4,963,143	10/16/90	Pinnow	~~604~~	14	4/3/89
	AD	5,098,426	3/24/92	Sklar et al.	~~606~~	~~15~~	2/6/89
	AE	5,312,398	5/17/94	Hobart et al.	~~606~~	~~14~~	4/13/92
	AF	5,531,740	7/2/96	Black	~~606~~	~~9~~	9/6/94
	AG	5,540,676	7/30/96	Freiberg	~~606~~	~~3~~	4/14/95
	AH	5,618,285	4/8/97	Zair	~~606~~	10	2/2/95
	AI	5,662,644	9/2/97	Swor	~~606~~	~~9~~	5/14/96
	AJ						

FOREIGN PATENTS OR PUBLISHED FOREIGN PATENT APPLICATIONS

		Document Number	Publication Date	Country / Patent Office	Class	Subclass	Translation Yes	Translation No
	AK	0 164 751 A2	12/18/85	EP	H 01	3/097	N/A	
	AL	EP 0 755 698 A2	1/29/97	EP	A61N	5/06	N/A	
	AM	DE 195 21 003 C1	6/96	DE	A 61 B	17/36		✓
	AN	WO 92/18057	10/29/92	PCT	A61B	17/22	~~N/A~~	✓
	AO							

OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)

	AP	
	AQ	
	AR	
	AS	
	AT	
	AU	
	AV	
	AW	
	AX	
	AY	
	AZ	

Examiner: [signature] Date Considered: January 21, 2000

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/018,104	02/03/98	HOBART J	WC PHAN-00100

EXAMINER	
SHAY, D	
ART UNIT	PAPER NUMBER
3739	13

QM32/0802

THOMAS B HAVERSTOCK
HAVERSTOCK & OWENS
260 SHERIDAN AVENUE
SUITE 420
PALO ALTO CA 94306

DATE MAILED: 08/02/00

DOCKETED

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

BEST AVAILABLE COPY

Office Action Summary

Application No.	Applicant(s)
09/618,104	Kobanteta al
Examiner	Group Art Unit
J. Sha	3739

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on May 19, 2000

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1-40 is/are pending in the application.

Of the above claim(s) 15, 16, 25-40 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-14, 17-24 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 13

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Action Summary

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3, 6-8, 11-14, and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sklar et al in combination with Dew ('969), Belkin et al and Anderson et al. Sklar et al teach a laser system including multiple lasers with a graphical interface and teach that it can be used for any type of surgery and with any type of laser and that the depth of the laser action can be input and displayed. Dew ('696) teaches the use of a carbon dioxide laser as a cutting laser in a laser system comprised of multiple lasers and teaches that the power of a pulse determines the amount of heat deposited in th tissue, Balkin et al teaches that carbon dioxide lasers can be used to heat, rather than cut tissue. Anderson teach the way parameters such as absorptivity, spot size, and pulse width interrelate to control the amount of energy absorbed by tissue. It would have been obvious to the artisan of ordinary skill to use a carbon dioxide laser as taught by Dew (696) in the graphical user interface of Sklar et al, since this is to be used with any laser, as taught by Sklar et al, to also configure the laser to coagulate as taught by Belkin et al, since this would render the device more versatile, at no extra cost, and is within the scope of one having ordinary skill in the art to shown by Anderson et al, and employ an articulated arm with refocussing optics, since these are notorious in the art for transporting infrared radiation such as that from Carbon dioxide lasers, official notice of which is hereby taken, thus producing a device such as claimed.

Claims 4, 5, 9, 10 and 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sklar et al in combination with Dew ('969), Anderson et al, and Belkin et al as applied to claims 1-3, 6-8, 12-14, and 17-18 above, and further in view of Assa et al. Assa et al teach a scanning handpiece and the equivalence of carbon dioxide and Erbium YAG lasers. Thus it would have been obvious to the artisan of ordinary skill to employ a handpiece as taught by Assa et al, since this allows more consistency of treatment and to employ an erbuim laser, since these are equivalent to the carbon dioxide laser, thus producing a device such as claimed.

Applicant argues that Sklar et al does not teach a medical laser-system with two or more lasers. This argument is not well founded in view of the disclosure at column 16, lines 60-66 of Sklar et al. Similarly the argument drawn to Dew ('969) are unfounded figure 2 of Dew ('969) clearly shows a laser system with multiple lasers and a controller with a timer to time length of the pulse. There is no disclosure either express or implied in Dew ('969) that the system can be used only once for coagulation. Thus it is clearly capable of producing a plurality of coagulative pulses, each of which would be controlled by the control system.

Since both Sklar et al and Dew ('969) teach a medical laser system comprising at least two lasers arguments drawn to the absence thereof in Belkin et al and Anderson et al do not rebut the prima facie case of obviousness established by the combination.

Applicant's arguments with respect to claims 1-24 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication should be directed to David Shay at telephone number (703) 308-2215.

David Shay:bhw
July 15, 2000

DAVID M. SHAY
PRIMARY EXAMINER
GROUP 330

FORM PTO-1449 (Modified)

U.S. Department of Commerce
Patent and Trademark Office

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Use Several Sheets If Necessary)

(37 CFR § 1.98(b))

Attorney Docket No.: SCI-00100	Serial No.: 09/018,104
Applicant: James L. Hobart *et al.*	
Filing Date: February 3, 1998	Group Art Unit: 3739

U.S. PATENT DOCUMENTS

Examiner Initials		Serial / Patent Number	Issue Date	Applicant / Patentee	Class	Subclass	Filing Date
	AA	3,596,514	8/3/71	Mefferd et al.	73	190	12/2/68
	AB	3,720,213	3/13/73	Hobart et al.	128	395	2/5/71
	AC	3,783,407	1/1/74	Mefferd et al.	331	94.5 C	9/26/72
	AD	Re. 31,279	1/14/83	Mefferd et al.	372	107	11/5/79
	AE	3,868,592	2/25/75	Yarborough et al.	331	94.5 C	5/30/73
	AF	3,873,941	3/25/75	Yarborough et al.	331	94.5 L	5/30/73
	AG	3,934,210	1/20/76	Yarborough et al.	331	94.5 C	5/30/74
	AH	3,995,166	11/30/76	Hobart et al.	250	566	4/16/75
	AI	4,150,342	4/17/79	Johnston, Jr. et al.	331	94.5 S	7/5/77
	AJ	4,378,600	3/29/83	Hobart	372	62	5/4/81
	AK	4,500,996	2/19/85	Sasnett et al.	372	19	3/31/82
	AL	4,864,578	9/5/89	Proffitt et al.	372	20	3/16/87
	AM	4,939,739	7/3/90	Hobart et al.	372	107	4/24/89
	AN	4,949,358	8/14/90	Kantorski et al.	372	94	4/25/88
	AO	5,023,886	6/11/91	Hobart et al.	372	99	12/1/88
	AP	5,033,061	7/16/91	Hobart et al.	372	107	6/11/90
	AQ	5,052,017	9/24/91	Hobart et al.	372	99	6/8/90
	AR	5,123,028	6/16/92	Hobart et al.	372	95	10/12/90
	AS	5,140,606	8/18/92	Yarborough et al.	372	64	10/12/90
	AT	5,300,066	4/5/94	Manoukian et al.	606	15	6/23/92
	BU	5,335,242	8/2/94	Hobart et al.	372	95	5/4/93
	BV	5,375,132	12/20/94	Connors et al.	372	34	5/5/93
	BW	5,585,698	12/17/96	Langhans et al.	315	200R	12/14/95

FOREIGN PATENTS OR PUBLISHED FOREIGN PATENT APPLICATIONS

		Document Number	Publication Date	Country / Patent Office	Class	Subclass	Translation Yes	Translation No
	BX	WO 96/41577	12/27/96	PCT	A61B	17/36		X

OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)

	CA	Anderson et al., "Selective Photothermolysis: Precise Microsurgery by Selective Absorption of Pulsed Radiation," American Association for the Advancement of Science, Volume 220, April 1983, pp.524-527, US
	CB	

Examiner: [signature] Date Considered: 7/11/2000

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

PATENT
Attorney Docket No.: SCI-00100

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Group Art Unit: 3739
James L. Hobart et al.	Examiner: Shay, D.
Serial No.: 09/018,104	
Filed: February 3, 1998	**RESPONSE TO OFFICE ACTION MAILED August 2, 2000**
For: **DUAL MODE LASER DELIVERY SYSTEM PROVIDING CONTROLLABLE DEPTH OF TISSUE ABLATION AND CORRESPONDING CONTROLLABLE DEPTH OF COAGULATION**	260 Sheridan Avenue, Suite 420 Palo Alto, California 94306 (650)833-0160

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir/Madam:

AMENDMENT

In the Claims:

Please amend the claims as follows:

1. (Twice Amended) A medical laser delivery apparatus for delivering one or more pulses to an area of tissue to be treated and generating a region of coagulation to a controllable coagulation depth under a surface of the area of tissue comprising a laser source

CERTIFICATE OF MAILING (37 CFR § 1.8(a))

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the U.S. Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the: Assistant Commissioner for Patents, Washington D.C. 20231

HAVERSTOCK & OWENS LLP

Date 10/2/00 By: _____

for generating a series of one or more non-ablative pulses to be delivered to the area of tissue to be treated in order to raise a temperature at the surface of the area of tissue to be treated to a temperature sufficient to generate coagulation at the coagulation depth when the laser source is in a coagulation mode, wherein the laser source comprises two or more lasers which are combined into a single laser wavelength output to provide the one or more non-ablative pulses.

8. (Twice Amended) The medical laser delivery apparatus as claimed in claim 1 wherein [at least one of the lasers has] the apparatus is configured to generate laser pulses with [a] short penetration depths.

9. (Twice Amended) The medical laser delivery apparatus as claimed in claim 8 wherein [at least one of] the two or more lasers [is an] are erbium lasers.

10. (Twice Amended) The medical laser delivery apparatus as claimed in claim 9 [8] wherein the erbium lasers [is an] are Er:YAG lasers.

11. (Twice Amended) A medical laser comprising:

a. a laser source having two or more lasers which are combined for generating a laser beam having a predetermined absorption wavelength, wherein the absorption wavelength forms a predetermined coagulation depth in response to an ablative laser pulse; and

b. a laser control system coupled for controlling the laser source for generating a plurality of coagulative laser pulses, such that each such coagulative laser pulse is delivered in sequence to a target area to form a coagulation region deeper than the predetermined coagulation depth.

17. (Twice Amended) A medical laser delivery apparatus for treating an area of tissue comprising:

a. a laser source having two or more lasers which are combined into a single laser wavelength output by a combining apparatus for generating a series of one or more laser pulses each having a strength and a duration;

b. a laser delivery system coupled to the laser source for delivering the laser pulses from the laser source to the area of tissue being treated;

c. a control system coupled to the laser source for controlling generation of the laser pulses from the laser source, wherein the laser source operates in both an ablation mode and a coagulation mode such that when in the ablation mode, the strength and duration of the laser pulses are sufficient to ablate tissue at the area of tissue being treated to a controllable ablation depth and when in the coagulation mode, the strength and duration of the laser pulses are sufficient to generate a coagulation region having a controllable coagulation depth within the tissue remaining at the area of tissue being treated without ablating any tissue.

23. (Twice Amended) The medical laser delivery apparatus as claimed in claim 22 wherein [at least one of] the two or more lasers [is an] are erbium lasers.

24. (Twice Amended) The medical laser delivery apparatus as claimed in claim [22] 23 wherein the erbium lasers [is an] are Er:YAG lasers.

REMARKS

To further advance the prosecution of the instant application in view of a Final Office Action and to place the Claims in better form for allowance the applicants submits the above amendments.

The applicants respectfully appeal for further examination and reconsideration in view of the above amendment and the remarks set forth below.

Prior to this amendment, Claims 1-14 and 17-24 were pending. Within the Office Action, Claims 1-14 and 17-24 have been rejected. Claims 1, 8-11, 17, 23 and 24 have been amended. Accordingly, Claims 1-14 and 17-24 are still pending.

Rejections Under 35 U.S.C. § 103

Within the Office Action, Claims 1-3, 6-8, 11-14 and 17-19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,098,426 to Sklar et al. (hereinafter "Sklar") in combination with U.S. Patent No. 4,672,969 to Dew (hereinafter "Dew"), U.S. Patent No. 5,620,435 to Belkin et al. (hereinafter "Belkin") and the article entitled "Selective

Photothermolysis: Precise Microsurgery by Selective Absorption of Pulsed Radiation" by R. Rox Anderson and John A. Parrish (hereinafter "Anderson").

The teachings of Sklar are applied as the primary reference in a U.S.C. 103(a) rejection of Claims 1-3, 6-8, 11-14, and 17-19 in the instant application. The reference to Sklar is not considered by the applicants to be analogous art for the reasons stated below. The teachings of Sklar are directed to a system and method for accurately controlling and positioning laser sources, specifically during surgery. The current invention is directed to a laser delivery apparatus for delivering one or more pulses to an area of tissue to be treated and generating a region of *coagulation* to *a controllable coagulation* depth under a surface of the area of tissue and the configuration of the laser source used to accomplish controllable coagulation.

According to Sklar "a limiting factor to the duration of the operation under these procedures (viz. Prior Art procedures) is the surgeon's reaction time while focusing on the target and the patients movement while the surgeon is trying to find the target and react to the target recognition by firing the laser. [Sklar, column 5, lines 13-19] In view of these prior art limitations, Sklar teaches a system for performing precision laser surgery which includes an imaging system for providing a surgeon with precision tracking and topographical information regarding the surgical target area. [Sklar, Abstract] Sklar states that "it is well appreciated that the limitations on the achievable accuracy and control of laser surgical instruments today is no longer paced by the development of laser technology, but by the imaging and tracking technologies needed to efficiently use the laser." [Sklar, column 2, lines 39-43] Therefore, the entire teachings of Sklar are directed to laser tracking and not a laser delivery system in accordance with the teachings of the present Application. Even if the teachings of Sklar in combination with the teachings of Dew, Belkin and Anderson were appropriate, Sklar fails to teach the dual mode laser source comprising two or more lasers for providing a laser beam at a single wavelength or absorption wavelength for generating a plurality of *coagulative laser pulses* as recited in the claims of the instant application.

It is clear from the description that the tracking system of Sklar can be used with any number of laser sources. Sklar states that "the therapeutic laser may be a frequency multiplied solid state laser which may be either flash lamp or diode pumped, or an argon, argon pumped dye, excimer, excimer pumped dye, nitrogen, nitrogen pumped dye, or any host of different lasers or combinations thereof." [Sklar, column 16, lines 60-68] The mere recitation of a "combination" of lasers does not suggest or teach the particular configuration of lasers claimed in the instant application. The recitation of a "combination" of lasers is interpretable to mean

independently operable lasers, combination laser and pumping lasers and any other imaginable "combination."

Dew teaches a laser healing method to effect wound closure and reconstruction of biological tissue. Optical energy is applied to produce thermal heating of biological tissue to a degree suitable for denaturing the tissue proteins such that the collagenous elements of the tissue form a biological glue to seal and reconstruct the tissue being heated. [Dew, Abstract] The system of Dew includes a laser 20. Dew teaches a marker laser 30 which is coaligned with the infrared beam of the laser 20. Further, Dew teaches that an auxiliary source of optical energy 50 can be incorporated into the apparatus to emit radiation having a wavelength which is intensely absorbed by biological tissue. Dew does not teach a medical laser with a laser source with two or more lasers which are combined for generating a laser beam at a single wave length or absorption wavelength for generating a plurality of coagulative laser pulses as recited in the claims of the instant application.

Belkin teaches a method for welding ocular tissues to each other using a carbon dioxide laser. [Belkin, col. 2, lines 35-44] Belkin does not teach a medical laser with a laser source with two or more lasers which are combined for generating a laser beam and a laser control system coupled for controlling the laser source for generating a plurality of coagulative laser pulses.

Anderson teaches a scheme for confining thermally mediated radiation damage to chosen pigmented targets. [Anderson, p. 524] The technique relies on selective absorption of a brief radiation pulse to generate and confine heat at certain pigmented targets. [Anderson, p. 524] Anderson does not teach a medical laser with a laser source with two or more lasers which are combined for generating a laser beam and a laser control system coupled for controlling the laser source for generating a plurality of *coagulative* laser pulses.

Accordingly, neither Sklar, Dew, Belkin, Anderson nor their combination teach a medical laser with a laser source with two or more lasers which are combined for generating a laser beam at a single wave length or a single predetermined absorption wavelength and a laser control system coupled for controlling the laser source for generating a plurality of coagulative laser pulses.

The independent Claim 1 is directed to a medical laser delivery apparatus for delivering one or more pulses to an area of tissue to be treated and generating a region of coagulation to a controllable coagulation depth under a surface of the area of tissue comprising a laser source for

generating a series of one or more non-ablative pulses to be delivered to the area of tissue to be treated in order to raise a temperature at the surface of the area of tissue to be treated to a temperature sufficient to generate coagulation at the coagulation depth when the laser source is in a coagulation mode. Claim 1 has been amended to recite that the laser source comprises two or more lasers which are combined into a single laser wavelength output to provide the one or more *non-ablative* pulses. As discussed above, neither Sklar, Dew, Belkin, Anderson nor their combination teach a medical laser with a laser source with two or more lasers which are combined for generating a laser beam and a laser control system coupled for controlling the laser source for generating a plurality of coagulative laser pulses with a single laser wavelength output. For at least these reasons, the independent Claim 1 is allowable over the teachings of Sklar, Dew, Belkin, Anderson and their combination.

Claims 2, 3 and 6-8 are all dependent on the independent Claim 1. As described above, the independent Claim 1 is allowable over the teachings of Sklar, Dew, Belkin, Anderson and their combination. Accordingly, Claims 2, 3 and 6-8 are all also allowable as being dependent upon an allowable base Claim.

The independent Claim 11 is directed to a medical laser comprising a laser source having two or more lasers which are combined for generating a laser beam having a predetermined absorption wavelength, wherein the absorption wavelength forms a predetermined coagulation depth in response to an ablative laser pulse; and a laser control system coupled for controlling the laser source for generating a plurality of coagulative laser pulses, such that each such coagulative laser pulse is delivered in sequence to a target area to form a coagulation region deeper than the predetermined coagulation depth. As discussed above, neither Sklar, Dew, Belkin, Anderson nor their combination teach a medical laser with a laser source with two or more lasers which are combined for generating a laser beam having a predetermined absorption wavelength and a laser control system coupled for controlling the laser source for generating a plurality of *coagulative laser pulses*. For at least these reasons, the independent Claim 11 is therefore allowable over the teachings of Sklar, Dew, Belkin, Anderson and their combination.

Claims 12-14 are all dependent on the independent Claim 11. As described above, the independent Claim 11 is allowable over the teachings of Sklar, Dew, Belkin, Anderson and their combination. Accordingly, Claims 12-14 are all also allowable as being dependent upon an allowable base claim.

The independent Claim 17 is directed to a medical laser delivery apparatus for treating an area of tissue. The medical laser delivery apparatus comprises a laser source with two or more lasers which are combined into a single laser wavelength output by a combining apparatus for generating a series of one or more laser pulses each having a strength and a duration. Claim 17 further includes a control system is coupled to the laser source for controlling generation of the laser pulses from the laser source, wherein the laser source operates in both an ablation mode and a coagulation mode such that when in the ablation mode, the strength and duration of the laser pulses are sufficient to ablate tissue at the area of tissue being treated to a controllable ablation depth and when in the coagulation mode, the strength and duration of the laser pulses are sufficient to generate a coagulation region having a controllable coagulation depth within the tissue remaining at the area of tissue being treated without ablating any tissue. As discussed above, neither Sklar, Dew, Belkin, Anderson nor their combination teach a medical laser with a laser source with two or more lasers which are combined into a single laser and a control system coupled for controlling the laser source for generating a plurality of coagulative laser pulses. For at least these reasons, the independent Claim 17 is therefore allowable over the teachings of Sklar, Dew, Belkin, Anderson and their combination.

Claims 18 and 19 are both dependent on the independent Claim 17. As described above, the independent Claim 17 is allowable over the teachings of Sklar, Dew, Belkin, Anderson and their combination. Accordingly, Claims 18 and 19 are both also allowable as being dependent upon an allowable base Claim.

Within the Office Action, Claims 4, 5, 9, 10 and 20-24 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Sklar in combination with Dew, Anderson, Belkin and further in view of U.S. Patent No. 5,938,657 to Assa et al. (hereinafter "Assa"). Assa teaches an apparatus for delivering energy within continuous outline. Claims 4, 5, 9 and 10 are all dependent on the independent Claim 1. As described above, the independent Claim 1 is allowable over the teachings of Sklar, Dew, Belkin, Anderson and their combination. Accordingly, Claims 4, 5, 9 and 10 are all also allowable as being dependent upon an allowable base Claim.

Claims 20-24 are all dependent on the independent Claim 17. As described above, the independent Claim 17 is allowable over the teachings of Sklar, Dew, Belkin, Anderson and their combination. Accordingly, Claims 20-24 are all also allowable as being dependent upon an allowable base claim.

For the reasons given above, Applicants respectfully submit that the claims are in a condition for allowance, and allowance at an early date would be appreciated. Should the Examiner have any questions or comments, they are encouraged to call the undersigned at (650) 833-0160 to discuss the same so that any outstanding issues can be expeditiously resolved.

Respectfully submitted,
HAVERSTOCK & OWENS LLP

Dated: October 2, 2000

By: Jonathan O. Owens

Jonathan O. Owens
Reg. No.: 37,902

Attorneys for Applicant

PATENT
Attorney Docket No.: SCI-00100

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Group Art Unit: 3739
James L. Hobart et al.	Examiner: Shay, D.
Serial No.: 09/018,104	
Filed: February 3, 1998	**RESPONSE TO OFFICE ACTION**
	MAILED September 17, 2001
For: **DUAL MODE LASER DELIVERY SYSTEM PROVIDING CONTROLLABLE DEPTH OF TISSUE ABLATION AND CORRESPONDING CONTROLLABLE DEPTH OF COAGULATION**	260 Sheridan Avenue, Suite 420 Palo Alto, California 94306 (650)833-0160

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir/Madam:

REMARKS

The Applicant respectfully requests further examination and reconsideration in view of the arguments set forth below. Claims 1-14, 17-24 and 41-49 were pending in this application. Within the Office Action, Claims 1-14, 17-24 and 41-49 have all been rejected. Claims 1-14, 17-24 and 41-49 are still pending in this application.

Rejections Under 35 U.S.C. § 112

Claims 41-49 have been rejected under 35 U.S.C. 112, first paragraph, for containing subject matter which was not described in the specification in such a way as to convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Within the Office Action it is specifically stated that the originally filed disclosure is silent on the use of a single wavelength. The Applicants respectfully traverse this rejection.

Within the originally filed disclosure it is specifically stated that

> the laser system of the preferred embodiment of the present invention is schematically illustrated in Figure 3. The laser generation system housing 30 includes the laser source 31 from which the laser beam 37 is provided. The laser source 31 preferably includes two erbium lasers 32 and 34 which generate the laser beams 33 and 35, respectively. Alternatively, any other appropriate short penetration length laser source can be used within the system of the present invention. The two laser beams 33 and 35 are combined into a single laser output 37 by the galvanometer 36 which switches between the two laser outputs 33 and 35. The galvanometer 36 then provides the laser output 37 from the laser source 31. [Specification, Page 7, lines 8-15]

A laser is by definition an optical device which generally produces light within a narrow wavelength range. Unless the laser source is a femtosecond pulsed laser source, the laser beam will by definition be a beam of light within a narrow wavelength range. A laser comprises a laser gain medium with a meta-stable excited state, and a laser cavity, to reflect light repetitively through the laser gain medium. Lasing occurs by using some means to pump electrons up into the meta-stable excited state to create a population inversion of electrons. This up pumping is then followed by stimulated relaxation from the meta-stable excited state to a lower energy state. The relaxation is driven by stimulated emission of photons as electrons in the meta-stable excited state make transitions to a lower energy state, most typically the ground state. Laser media with a multiplicity of meta-stable excited states and, therefore, a multiplicity of transitions are possible. However, except under very special conditions, one transition is typically several hundred-fold more probable than the other transitions and a medium will only lase from one transition for any given set of lasing conditions and, hence, will only produce one narrow wavelength band of laser light at one time. In order to induce one of the other less probable transitions, to produce laser light at a different wavelength, requires special manipulation of the optics within the laser cavity, special pumping of the laser medium or in some cases geometric manipulation of the laser cavity. Regardless, in the absence of extraordinary conditions, the laser

light that will be produced for any given laser medium will correspond to light produced from the most probable laser transition and the laser beam will only have one narrow emission band.

Within the instant application the applicants refer to the laser beam, which is by definition a beam of light within a narrow wavelength range. The Applicants do not refer to a stream of multi-color laser beams. Further, the applicants refer to "the laser source 31 which preferably includes two erbium lasers 32 and 34 which generate the laser beams 33 and 35." [Specification, page 7, lines 10-11] A person skilled in the art will understand that in the absence of extraordinary circumstances, the two erbium lasers will lase at very nearly the same single wavelength and that the combination of the laser beams 33 and 35 will produce the laser beam 37 or laser output at essentially the same wavelength. For at least these reasons it is requested that the rejection under 35 U.S.C. 112, first paragraph, be withdrawn.

Claims 2-5, 11-14, 17-23 and 49 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. In the Office Action, it is specifically stated that in Claims 2 and 29 it is unclear what is encompassed by the term "arm feature". Further, it is stated within the Office Action that with regards to Claims 11 and 17 the term "two or more lasers which are combined in an alternating pattern" is unclear. It is further stated within the Office Action that it is unclear how the beams are combined in an alternating fashion wherein a plurality of coagulative laser pulses are generated and delivered in sequence to a target area. The Applicant respectfully traverses the rejection for the following reasons.

Within the originally filed disclosure the applicant clearly described an arm feature. Specifically the applicant states that

> the laser system of the present invention includes the articulated arm 38 to deliver the laser from the laser head 36 to the scanner handpiece 54. Within the arm 38 are a series of focussing lenses 46, 50 and 52 which are utilized to refocus the laser beam 37 as it travels through the arm 38. As is well known in the art, a laser beam traveling over a distance will converge until it reaches its focal point and then will tend to naturally expand as it travels past its focal point. The focussing lenses 46, 50 and 52 refocus the laser beam 37 so that the laser beam delivered to the scanner handpiece 54 is the same diameter as the laser beam output from the laser source 31. [Specification, Page 14, lines 13-20]

Accordingly an arm feature as recited in the Claims 2 and 29 is clearly described in the specification.

Regarding Claims 11 and 17, again attention is directed to the specification wherein it is specifically stated that "the two laser beams 33 and 35 are combined into a single laser output 37

by the galvanometer 36 which switches between the two laser outputs 33 and 35." [Specification, Page 7, lines 13-14] Thus, it is clearly described within the specification how the two laser beams 33 and 35 are used in an alternating, or equivocally a switching fashion, to form the combined output laser beam 37.

Rejections Under 35 U.S.C. § 102

Within the Office Action, Claims 1, 2, 11 and 17 have been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,125,922 to Dwyer (hereafter "Dwyer"). The Applicants respectfully traverse this rejection. No description to the teachings of Dwyer or detailed reasons for the rejection is given within the Office Action.

Dwyer teaches a laser device that switches between a first laser beam with a first set of laser conditions and a second laser beam with a second set of laser conditions. Dwyer teaches that by manipulating the optics within the cavity of a Nd:YAG laser, the most probable lasing transition producing laser light 1.06 microns, can effectively be shut off such that lasing can occur to produce laser light at 1.3 microns. [Dwyer, Abstract] In other words, Dwyer teaches a laser device with a tunable laser cavity for switching between two lasing conditions and thus producing two wavelengths, only one of which is generated under any one set of laser conditions.

Dwyer also teaches that a system can have two lasers with one of the lasers operating at 1.06 microns and the other laser operating at 1.3 microns, such that a surgeon can switch between the two lasers for cauterizing and cutting, respectively. However, Dwyer does not teach using one or more lasers pulsed in different ways to produce different tissue effects that are combined into a single laser beam to produce ablative and non-ablative laser pulses in a controlled fashion. In fact Dwyer does not teach combining laser beams at all.

In contrast to the teachings of Dwyer, the instant invention is directed to a laser system that is capable of operating in an ablation mode and a coagulation mode by using two or more laser sources operating at the same wavelength, which are combined in a single laser beam having a single wavelength, and wherein the pulse sequences are selectable to achieve the effects of ablating tissue or coagulating tissue. No where is this taught in the prior art.

The independent Claim 1 is directed to a medical laser delivery apparatus for delivering one or more pulses to an area of tissue to be treated and generating a region of coagulation to a controllable coagulation depth under a surface of the area of tissue. The system has a laser source for generating a series of one or more non-ablative laser pulses to be delivered to the area of tissue to be treated in order to raise a temperature at the surface of the area of tissue to be

treated to a temperature sufficient to generate coagulation at the coagulation depth when the laser source is in a coagulation mode, wherein the laser source comprises two or more lasers for generating two or more corresponding laser beams which are alternated to produce a single laser output which provides the series of one or more non-ablative laser pulses. As discussed above, Dwyer fails to teach a medical laser with a laser source having two or more lasers which are alternated to produce a single laser output which provides the series of one or more non-ablative laser pulses. For at least these reasons, the independent Claim 1 is allowable over the teachings of Dwyer.

Claims 2 is dependent on the independent Claim 1. As described above, the independent Claim 1 is allowable over the teachings of Dwyer. Accordingly, Claim 2 is allowable as being dependent upon an allowable base claim.

The independent Claim 11 is directed to medical laser comprising a laser source having two or more lasers which are combined in an alternating fashion for generating a laser output having a predetermined absorption, wherein the predetermined absorption forms a predetermined coagulation depth. The medical laser of Claim 11 also has a laser control system coupled to the laser source for controlling the laser source to generate a plurality of coagulative laser pulses from the laser output, such that each such coagulative laser pulse is delivered in sequence to a target area. As discussed above, Dwyer fails to teach a medical laser with a laser source with two or more lasers which are combined in an alternating fashion for generating a laser output to generate a plurality of coagulative laser pulses. For at least these reasons, the independent Claim 11 is allowable over the teachings of Dwyer.

The independent Claim 17 is directed to a medical laser delivery apparatus for treating an area of tissue. The medical laser delivery apparatus has a laser source having two or more lasers which are combined in an alternating fashion into a single laser output by a combining apparatus for generating a series of one or more laser pulses each having a strength and a duration. The apparatus also has a laser delivery system coupled to the laser source for delivering the laser pulses from the laser source to the area of tissue being treated and a control system coupled to the laser source for controlling generation of the laser pulses from the laser source, wherein the laser source operates in both an ablation mode and a coagulation mode such that when in the ablation mode, the strength and duration of the laser pulses are sufficient to ablate tissue at the area of tissue being treated to a controllable ablation depth and when in the coagulation mode, the strength and duration of the laser pulses are sufficient to generate a coagulation region having a controllable coagulation depth within the tissue remaining at the area of tissue being treated

without ablating any tissue. As discussed above, Dwyer fails to teach a medical laser delivery apparatus which has two or more lasers which are combined in an alternating fashion into a single laser output and a control system coupled for controlling the laser source for generating laser pulses with the strength and duration for both ablation and coagulation. For at least these reasons, the independent Claim 17 is allowable over the teachings of Dwyer.

Rejections Under 35 U.S.C. § 103

Within the Office Action, Claims 1-3, 6-8, 11-14, 17-19 and 43-49 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,098,426 to Sklar et al. (hereinafter "Sklar") in combination with U.S. Patent No. 4,672,969 to Dew (hereinafter "Dew"), U.S. Patent No. 5,620,435 to Belkin et al. (hereinafter "Belkin"), the article entitled "Selective Photothermolysis: Precise Microsurgery by Selective Absorption of Pulsed Radiation" by R. Rox Anderson and John A. Parrish (hereinafter "Anderson") and U.S. Patent No. 5,125,922 to Dwyer (hereinafter "Dwyer"). The Applicant respectfully traverses the rejection for the following reasons.

A prima facie case of obviousness, warranting the combination of these five (5) references has not been set forth within the Office Action. In order to combine references to support a prima facie case of obviousness, there must be some suggestion or motivation to modify a reference or combine the references, there must be a reasonable expectation of success and the references must teach all of the claimed elements. The Applicant find no suggestion within the references themselves or within the general knowledge of the art to combine such a large number of references. Further, each of the references taken singularly or in combination do not teach or suggest the combination of features taught and claimed in the instant application. (M.P.E.P. 2124).

The teachings of Sklar are applied as the primary reference in a U.S.C. 103(a) rejection of Claims 1-3, 6-8, 11-14, 17-19 and 43-49 in the instant application. The teachings of Sklar have been fully characterized in previous communications. Briefly, the teachings of Sklar are directed to a system and method for accurately controlling and positioning laser sources, specifically during surgery. According to Sklar "a limiting factor to the duration of the operation under these procedures (viz. Prior Art procedures) is the surgeon's reaction time while focusing on the target and the patients movement while the surgeon is trying to find the target and react to the target recognition by firing the laser." [Sklar, column 5, lines 13-19] In view of these prior art limitations, Sklar teaches a system for performing precision laser surgery which includes an

imaging system for providing a surgeon with precision tracking and topographical information regarding the surgical target area. [Sklar, Abstract] Sklar states that "it is well appreciated that the limitations on the achievable accuracy and control of laser surgical instruments today is no longer paced by the development of laser technology, but by the imaging and tracking technologies needed to efficiently use the laser." [Sklar, column 2, lines 39-43]

Sklar does not teach a laser device, or a laser system, with a laser source having two or more lasers that produce laser beams and which are alternated and combined to generate a single laser output for producing coagulation laser pulses as currently recited in each of the Independent Claims 1, 11 and 17. Nor does Sklar teach a laser device, or a laser system, for generating both ablation and coagulation laser pulses as recited in Independent Claim 41. Further, Sklar does not teach an arm structure for guiding the single laser output, as recited in Claims 3, 14 and 49, or a plurality of refocussing lenses for focussing the single laser output, as recited in claims 5, 14 and 49.

Dew teaches a laser healing method to effect wound closure and reconstruction of biological tissue. Optical energy is applied to produce thermal heating of biological tissue to a degree suitable for denaturing the tissue proteins such that the collagenous elements of the tissue form a biological glue to seal and reconstruct the tissue being heated. [Dew, Abstract] The system of Dew includes a laser 20. Dew teaches a marker laser 30 which is coaligned with the infrared beam of the laser 20. Dew teaches that an auxiliary source of optical energy 50 can be incorporated into the apparatus to emit radiation having a wavelength which is intensely absorbed by biological tissue.

Dew does not teach a laser source with two or more lasers that produce laser beams that are alternated and combined to generate a single laser output for generating coagulation laser pulses as currently recited in each of the Independent Claims 1, 11 and 17 or for generating both ablation and coagulation laser pulses as recited in Independent Claim 41. Further, Dew does not teach an arm structure for guiding the single laser output, as recited in Claims 3, 14 and 49, or a plurality of refocussing lenses for focussing the single laser output, as recited in claims 5, 14 and 49. Nor does Dew teach a user interface, the elements of which are recited in claims 7, 12, and 44-46.

Belkin teaches a method for welding ocular tissues to each other using a carbon dioxide laser. [Belkin, col. 2, lines 35-44] Belkin does not teach a medical laser with a laser source with two or more lasers for generating a plurality of coagulative laser pulses.

Belkin does not teach a laser or a laser system with a laser source having two or more lasers that produce laser beams that are alternated and combined to generate a single laser output for generating coagulation laser pulses as currently recited in each of the independent Claims 1, 11 and 17 or for generating both ablation and coagulation laser pulses as recited in Independent Claim 41. Further, Belkin does not teach an arm structure for guiding the single laser output, as recited in Claims 3, 14 and 49, or a plurality of refocussing lenses for focussing the single laser output, as recited in claims 5, 14 and 49. Nor does Belkin teach a user interface, the elements of which are recited in claims 7, 12, and 44-46.

Anderson teaches a scheme for confining thermally mediated radiation damage to chosen pigmented targets. [Anderson, p. 524] The technique relies on selective absorption of a brief radiation pulse to generate and confine heat at certain pigmented targets. [Anderson, p. 524] Anderson does not teach a medical laser with a laser system as currently claimed. Specifically, Anderson does not teach laser source with two or more lasers that produce laser beams which are alternated and combined to generate a single laser output for generating coagulation laser pulses as currently recited in each of the Independent Claims 1, 11 and 17, or for generating both ablation and coagulation laser pulses as recited in Independent Claim 41. Further, Anderson does not teach an arm structure for guiding the single laser output, as recited in Claims 3, 14 and 49, or a plurality of refocussing lenses for focussing the single laser output, as recited in claims 5, 14 and 49. Nor does Dew teach a user interface, the elements of which are recited in claims 7, 12, and 44-46.

Dwyer teaches laser device which uses a means for switching the laser output between two laser wavelengths. The means for switching includes a prism which effectively bleeds the cavity from a dominant laser wavelength such that conditions for stimulated emission transitions producing laser light at 1.3 micron is achieved. [Dwyer, Abstract] In each case, the laser device is producing only one wavelength for any one set of laser conditions. Dwyer, however does not teach combining two or more lasers to generate a single laser output or laser beam as taught and claimed in the instant application.

As stated above, the current invention is a laser system that utilizes multiple lasers which produce multiple laser beams. The multiple laser beams are alternated with a galvanometer or other suitable device to produce a single laser output which generates coagulation laser pulses. The laser system preferably also is configured to generate ablation laser pulses. The single laser output is preferably guided to a target tissue through an articulated arm with a series of refocussing optics. The system preferably has a user interface that allows a user to select laser

pulse patterns, target sizes and operating modes. The interface preferably is a graphical user interface that displays the selected laser pulse pattern and allows the user to select a desired ablation depth value and coagulation depth value. The combinations of features claimed in the instant application are neither taught or suggested by Sklar, Dew, Belkin, Anderson, Dwyer nor their combination.

The independent Claim 1 is directed to a medical laser delivery apparatus for delivering one or more pulses to an area of tissue to be treated and generating a region of coagulation to a controllable coagulation depth under a surface of the area of tissue. The system has a laser source for generating a series of one or more non-ablative laser pulses to be delivered to the area of tissue to be treated in order to raise a temperature at the surface of the area of tissue to be treated to a temperature sufficient to generate coagulation at the coagulation depth when the laser source is in a coagulation mode, wherein the laser source comprises two or more lasers for generating two or more corresponding laser beams which are alternated to produce a single laser output which provides the series of one or more non-ablative laser pulses. As discussed above, neither Sklar, Dew, Belkin, Anderson, Dwyer nor their combination teach a medical laser with a laser source with two or more lasers which are alternated to produce a single laser output which provides the series of one or more non-ablative laser pulses. For at least these reasons, the independent Claim 1 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination.

Claims 2, 3 and 6-8 are all dependent on the independent Claim 1. As described above, the independent Claim 1 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination. Accordingly, Claims 2, 3 and 6-8 are all also allowable as being dependent upon an allowable base claim.

The independent Claim 11 is directed to medical laser having a laser source having two or more lasers which are combined in an alternating fashion for generating a laser output having a predetermined absorption, wherein the predetermined absorption forms a predetermined coagulation depth. The medical laser of Claims 11 also has a laser control system coupled to the laser source for controlling the laser source to generate a plurality of coagulative laser pulses from the laser output, such that each such coagulative laser pulse is delivered in sequence to a target area. As discussed above, neither Sklar, Dew, Belkin, Anderson, Dwyer nor their combination teach a medical laser with a laser source with two or more lasers which are

combined in an alternating fashion for generating a laser output to generate a plurality of coagulative laser pulses. For at least these reasons, the independent Claim 11 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination.

Claims 12-14 are all dependent on the independent Claim 11. As described above, the independent Claim 11 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination. Accordingly, Claims 12-14 are all also allowable as being dependent upon an allowable base claim.

The independent Claim 17 is directed to a medical laser delivery apparatus for treating an area of tissue. The medical laser delivery apparatus has a laser source having two or more lasers which are combined in an alternating fashion into a single laser output by a combining apparatus for generating a series of one or more laser pulses each having a strength and a duration. The apparatus also has a laser delivery system coupled to the laser source for delivering the laser pulses from the laser source to the area of tissue being treated and a control system coupled to the laser source for controlling generation of the laser pulses from the laser source, wherein the laser source operates in both an ablation mode and a coagulation mode such that when in the ablation mode, the strength and duration of the laser pulses are sufficient to ablate tissue at the area of tissue being treated to a controllable ablation depth and when in the coagulation mode, the strength and duration of the laser pulses are sufficient to generate a coagulation region having a controllable coagulation depth within the tissue remaining at the area of tissue being treated without ablating any tissue. As discussed above, neither Sklar, Dew, Belkin, Anderson, Dwyer nor their combination teach a medical laser delivery apparatus which has two or more lasers which are combined in an alternating fashion into a single laser output and a control system coupled for controlling the laser source for generating laser pulses with the strength and duration for both ablation and coagulation. For at least these reasons, the independent Claim 17 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination.

Claims 18 and 19 are both dependent on the independent Claim 17. As described above, the independent Claim 17 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination. Accordingly, Claims 18 and 19 are both allowable as being dependent upon an allowable base claim.

The independent Claim 41 is directed to a dual mode medical laser system, for sequentially ablating and coagulating a region of target tissue with ablation laser pluses followed by coagulation laser pulses to the region of target tissues. The dual mode medical laser system has a laser source comprising a first laser and a second laser for generating a first laser beam and

a second laser beam at a same wavelength and a means to alternate between the first laser beam and the second laser beam to provide a single laser output to provide the ablation laser pulses and the coagulation laser pulses. The medical laser system also has a means to direct the single laser output to the region of the target tissue. As discussed above, neither Sklar, Dew, Belkin, Anderson, Dwyer nor their combination teach a medical laser delivery apparatus having a first and second laser that produce laser beams that are alternated to produce ablation and coagulation laser pulses from a single laser output. For at least these reasons, the new independent Claim 41 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination.

Claims 42-49 all dependent on the independent Claim 41. As described above, the independent Claim 41 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination. Accordingly, Claims 42-49 are all allowable as being dependent upon an allowable base claim.

Within the Office Action, Claims 4, 5, 9, 10, 20-24 and 42 have been further rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,098,426 to Sklar et al. (hereinafter "Sklar") in combination with U.S. Patent No. 4,672,969 to Dew (hereinafter "Dew"), U.S. Patent No. 5,620,435 to Belkin et al. (hereinafter "Belkin"), the article entitled "Selective Photothermolysis: Precise Microsurgery by Selective Absorption of Pulsed Radiation" by R. Rox Anderson and John A. Parrish (hereinafter "Anderson") and U.S. Patent No. 5,125,922 to Dwyer (hereafter "Dwyer") and further in view of U.S. Patent No. 5,938,657 to Assa et al. (hereinafter "Assa").

Assa teaches an apparatus for delivering energy with a continuous output and can not be combined with Sklar, Dew, Belkin, Anderson or Dwyer either singularly or in combination teach the combination of features taught and claimed in the instant application. Again, the inordinate number of combined references is inconsistent with establishing a prima facie case of obviousness and there is no hint, teaching or suggestion in the prior art to combine the references in a way which would produce the invention as claimed in the instant application.

Claims 4, 5, 9 and 10 are all dependent on the independent Claim 1. As described above, the independent Claim 1 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination. Accordingly, Claims 4, 5, 9 and 10 are all allowable as being dependent upon an allowable base claim.

Claims 20-24 are all dependent on the independent Claim 17. As described above, the independent Claim 17 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination. Accordingly, Claims 20-24 are all allowable as being dependent upon an allowable base claim.

Claim 42 is dependent on the independent Claim 41. As described above, the independent Claim 41 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination. Accordingly, Claim 42 is allowable as being dependent upon an allowable base claim.

For the reasons given above, Applicants respectfully submit that the claims are in a condition for allowance, and allowance at an early date would be appreciated. Should the Examiner have any questions or comments, they are encouraged to call the undersigned at (650) 833-0160 to discuss the same so that any outstanding issues can be expeditiously resolved.

Respectfully submitted,
HAVERSTOCK & OWENS LLP

Dated: November 16, 2001 By: Jonathan O. Owens

Jonathan O. Owens
Reg. No.: 37,902
Attorneys for Applicant

CERTIFICATE OF MAILING (37 CFR § 1.8(a))

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the U.S. Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the: Assistant Commissioner for Patents, Washington D.C. 20231

HAVERSTOCK & OWENS LLP

Date: 11-16-01 By: Jonathan O. Owens

Attorney Docket No.: SCI-00100

28960
PATENT .TRADEMARK OFFICE

HAVERSTOCK & OWENS LLP
162 North Wolfe Road
Sunnyvale, California 94086
(408) 530-9700

In re Application of: James L. Hobart et al.
Serial No.: 09/018,104
Filed: February 3, 1998
Entitled: DUAL MODE LASER DELIVERY SYSTEM PROVIDING CONTROLLABLE DEPTH OF TISSUE ABLATION AND CORRESPONDING CONTROLLABLE DEPTH OF COAGULATION

BOX CPA
Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

CONTINUED PROSECUTION APPLICATION (CPA) REQUEST TRANSMITTAL

entitled: This is a request for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) of prior application number 09/018,104filed on February 3, 1998 DUAL MODE LASER DELIVERY SYSTEM PROVIDING CONTROLLABLE DEPTH OF TISSUE ABLATION AND CORRESPONDING CONTROLLABLE DEPTH OF COAGULATION.

CERTIFICATION UNDER 37 CFR § 1.10

I hereby certify that this New Application and the documents referred to as enclosed herein are being deposited with the United States Postal Service on this date, March 13, 2001, in an envelope bearing "Express Mail Post Office To Addressee" Mailing Label Number EV086241261US addressed to: **BOX CPA**, Assistant Commissioner for Patents, Washington, D.C. 20231.

Juan Rascon
(Name of Person Mailing Paper)

Juan D. Rascon
Signature

1. X Enter the unentered amendment previously filed on November 16, 2001under 37 CFR 1.116 in the prior nonprovisional application.

2. Fee Calculation *(Based on the number of claims remaining as a result of the unentered amendment previously filed on November 16, 2001)*

CLAIMS AS FILED

	Number Filed	Number Extra	Rate	Basic Fee
				$740.00
Total Claims	31 - 20 =	11	$18.00	198.00
Independent Claims	4 - 3 =	1	$84.00	84.00
	Multiple Dependent claim(s), if any		$280.00	0.00
			Filing Fee Calculation	1,022.00

3. X Applicants entitled to small entity status

50% Filing Fee Reduction (if applicable) 511.00

4. Payment of Fees

X Check in the amount of $971.00 ($511.00 CPA filing fee plus $460.00 three month extension of time fee) enclosed.

5. X Authorization to Charge Additional Fees

The Commissioner is hereby authorized to charge any additional fees (or credit any overpayment) associated with this communication and which may be required under 37 CFR § 1.16 or § 1.17 to Account No. 08-1275 An originally executed duplicate of this transmittal is enclosed for this purpose.

6. X Address all future communications to:

HAVERSTOCK & OWENS LLP
ATTN: Jonathan O. Owens
162 North Wolfe Road
Sunnyvale, CA 94086

7. X Petition for extension of time. The undersigned attorney of record hereby petitions for an extension of time pursuant to 37 C.F.R. § 1.136 (a), as may be required, to file this CPA.

8. X Return Receipt Postcard

Dated: March 13, 2002

By: Jonathan O. Owens
Name: Jonathan O. Owens
Registration No.: 37,902

HAVERSTOCK & OWENS LLP
162 North Wolfe Road
Sunnyvale, California 94086
(408) 530-9700

In re Application of: James L. Hobart et al.
Serial No.: 09/018,104
Filed: February 3, 1998
Entitled: **DUAL MODE LASER DELIVERY SYSTEM PROVIDING CONTROLLABLE DEPTH OF TISSUE ABLATION AND CORRESPONDING CONTROLLABLE DEPTH OF COAGULATION**

BOX CPA
Assistant Commissioner for Patents
Washington, D.C. 20231

CONTINUED PROSECUTION APPLICATION (CPA)
REQUEST TRANSMITTAL

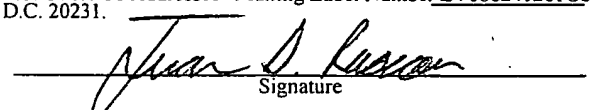
Sir:

This is a request for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) of prior application number 09/018,104filed on February 3, 1998
entitled: **DUAL MODE LASER DELIVERY SYSTEM PROVIDING CONTROLLABLE DEPTH OF TISSUE ABLATION AND CORRESPONDING CONTROLLABLE DEPTH OF COAGULATION.**

CERTIFICATION UNDER 37 CFR § 1.10

I hereby certify that this New Application and the documents referred to as enclosed herein are being deposited with the United States Postal Service on this date, March 13, 2001, in an envelope bearing "Express Mail Post Office To Addressee" Mailing Label Number EV086241261US addressed to: **BOX CPA**, Assistant Commissioner for Patents, Washington, D.C. 20231.

Juan Rascon
(Name of Person Mailing Paper)


Signature

1. X Enter the unentered amendment previously filed on November 16, 2001 under 37 CFR 1.116 in the prior nonprovisional application.

2. Fee Calculation *(Based on the number of claims remaining as a result of the unentered amendment previously filed on November 16, 2001)*

CLAIMS AS FILED

	Number Filed	Number Extra	Rate	Basic Fee
				$740.00
Total Claims	31 - 20 =	11	$18.00	198.00
Independent Claims	4 - 3 =	1	$84.00	84.00
Multiple Dependent claim(s), if any			$280.00	0.00
			Filing Fee Calculation	1,022.00

3. X Applicants entitled to small entity status

50% Filing Fee Reduction (if applicable) 511.00

4. Payment of Fees

X Check in the amount of $971.00 ($511.00 CPA filing fee plus $460.00 three month extension of time fee) enclosed.

5. X Authorization to Charge Additional Fees

The Commissioner is hereby authorized to charge any additional fees (or credit any overpayment) associated with this communication and which may be required under 37 CFR § 1.16 or § 1.17 to Account No. 08-1275
An originally executed duplicate of this transmittal is enclosed for this purpose.

5. X Address all future communications to:

HAVERSTOCK & OWENS LLP
ATTN: Jonathan O. Owens
162 North Wolfe Road
Sunnyvale, CA 94086

7. X Petition for extension of time. The undersigned attorney of record hereby petitions for an extension of time pursuant to 37 C.F.R. § 1.136 (a), as may be required, to file this CPA.

8. X Return Receipt Postcard

Dated: March 13, 2002

By: 
Name: Jonathan O. Owens
Registration No.: 37,902

Express Mail Label # EV086241261US
PATENT
Attorney Docket No.: SCI-00100

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Group:
	Art Unit: 3739
James L. Hobart *et al.*	Examiner: Shay, D.
Serial No.: 09/018,104	**REQUEST FOR A THREE MONTH EXTENSION OF TIME**
Filed: February 3, 1998	
For: **DUAL MODE LASER DELIVERY SYSTEM PROVIDING CONTROLLABLE DEPTH OF TISSUE ABLATION AND CORRESPONDING CONTROLLABLE DEPTH OF COAGULATION**	162 North Wolfe Road Sunnyvale, CA 94086 (408)530-9700

Assistant Commissioner of Patents
Washington, D.C. 20231

Sir:

Applicants hereby petition for a three month extension of time to answer the outstanding Final Office Action mailed on September 17, 2001 regarding the above-identified patent application. Please find a check enclosed in the amount of $971.00 which covers the Continued Prosecution Application (CPA) filing fee of $511.00 plus $460.00 to cover the three month extension fee.

Respectfully submitted,
HAVERSTOCK & OWENS LLP

Dated: March 13, 2002 By: Jonathan O. Owens

Jonathan O. Owens
Reg No.: 37,902
Attorneys for Applicant

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/018,104	02/03/1998	JAMES L. HOBART	PHAN-00100	9278

28960 7590 05/28/2002

HAVERSTOCK & OWENS LLP
162 NORTH WOLFE ROAD
SUNNYVALE, CA 94086

EXAMINER
SHAY, DAVID M

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 05/28/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/018,164	Hobart et al
Examiner	**Group Art Unit**
d. Shay	3739

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☑ Responsive to communication(s) filed on ~~November 16~~ March 13, 2002.

☑ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

☑ Claim(s) 1-14, 17-24, & 41-49 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☑ Claim(s) 1-14, 17-24 & 41-49 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Action Summary

The rejections set forth in the previous Office action are hereby repeated.

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 41-49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The originally filed disclosure is silent on the lasers producing the same wavelength.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 2-5, 11-14, 17-23, and 49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 2 and 49 exactly what is to be encompassed by the term "arm feature" is unclear. Claims 11 and 17 are indefinite as the meaning of the term "two or more lasers which are combined in an alternating pattern" is unclear. For the purposes of examination the term will be read as – two or more lasers each producing laser beams--. Claims 11 and 17 are further indefinite because it is unclear how the beams are combined "in an alternating fashion" wherein "a pluralilty of coagulative laser" pulses are generated and "delivered in sequence to a target area".

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 2, 11, and 17 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Dwyer et al.

7. Claims 1-3, 6-8, 11-14, 17-19, and 43-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sklar et al in combination with Dew ('969), Anderson et al, Belkin et al and Dwyer et al. Sklar et al teach a laser system including multiple lasers with a graphical interface and teach that it can be used for any type of surgery with any type of laser and that the depth of the laser action can be input and displayed. Dew ('969) teaches the use of a carbon dioxide laser operating at 10.6 microns as a cutting laser in laser system comprised of multiple lasers and teaches that the power of a pulse determines the amount of heat deposted in the tissue. Belkin et al teach that carbon dioxide lasers operating 10.6 mircrons can be used to heat, rather than cut tissue. Anderson et al teach the way parameters such as absorptivity spot size, and pulse width interrelate to control the amount of energy absorbed by tissue. Dwyer et al teach performing surgery by alternating cutting and coagulation. It would have been obvious to the artisan of ordinary skill to use a carbon dioxide laser as taught by Dew ('969) in the graphical user interface of Sklar et al, since this is to be used with any laser, as taught by Sklar, et al, to also configure the laser to coagulate as taught by Belkin et al, since this would render the device more versatile, at no extral cost and to

employ the particular laser parameters claimed since these provide no unexpected result, and are within the scope of one having ordinary skill in the art as shown to by Anderson et al to alternate cutting and coagulating pulses, since this enables bloodless surgery as taught by Dwyer et al; employ an articulated arm, since these are notorious in the art for transporting infrared radiation such as that from Carbon dioxide lasers, official notice of which has already been taken and to use a galvanometer to alternate the beams, since these are notorious for moving optical components official notice which is hereby taken thus producing a device such as claimed.

8. Claims 4, 5, 9, 10, 20-24 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sklar et al in combination with Dew ('969), Anderson et al, Belkin et al and Dwyer et al as applied to claims 1-3, 6-8 11-14, 17-19, 41, and 43-49 above, and further in view of Assa et al. Assa et al teach a scanning handpiece and the equivalence of carbon dioxide and Erbrium YAG lasers. Thus it would have been obvious to the artisan of ordinary skill to employ an handpiece as taught by Assa et al, since this allows more consistency of treatment and to employ an erbuim laser, since these are equivalent to the carbon dioxide laser, thus producing a device such as claimed.

9. Applicant asserts that the use of two lasers of the same type will result in the output beam being a single wavelength. The examiner must disagree, noting that Dwyer et al use the same type of laser to produce different wavelengths.

10. To extent that applicant argues the references teachings, they are argued separately without regard to what the combination would teach one having ordinary skill in the art.

11. Regarding the remarks filed November 16, 2001, the examiner reiterates that Dwyer et al teach the production of two wavelengths with a single laser. Regarding the indefiniteness rejection if the term "arm feature" is intended to refer to an articulated arm, the claim should be amended to reflect this.

Regarding the anticipation rejection, applicant has pointed to nothing which would indicate that the train of laser pulses of Dwyer et al all of which follow a common path regardless of wavelength should not be considered a beam. Regarding the obviousness rejection, the examiner notes that all reference are properly combined with proper motivations specifically set forth.

11. Applicant's arguments filed November 16, 2001 have been fully considered but they are not persuasive. The foregoing due to the above remarks.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to David Shay at telephone number (703) 308-2215.

David Shay:bhw

April 25, 2002

DAVID M. SHAY
PRIMARY EXAMINER
GROUP 330

EXPRESS MAIL LABEL NO. EV062940683US

PATENT
Attorney Docket No.: SCI-00100

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

James L. Hobart *et al.*

Serial No.: 09/018,104

Filed: February 3, 1998

For: **DUAL MODE LASER DELIVERY SYSTEM PROVIDING CONTROLLABLE DEPTH OF TISSUE ABLATION AND CORRESPONDING CONTROLLABLE DEPTH OF COAGULATION**

Group Art Unit: 3739

Examiner: Shay, D.

REQUEST FOR ONE MONTH EXTENSION OF TIME

162 North Wolfe Road
Sunnyvale, CA 94086
(408) 530-9700

Box CPA
Assistant Commissioner of Patents
Washington, D.C. 20231

Sir:

Applicant hereby petitions for a one month extension of time to answer the outstanding Final Office Action mailed May 28, 2002 regarding the above-identified patent application. Please find a check enclosed in the amount of $566.00 to cover the $55.00 extension fee for filing a Response within the first one month plus $511.00 for Continued Prosecution Application filing fee.

Respectfully submitted,
HAVERSTOCK & OWENS LLP

Dated: September 30, 2002

By: Jonathan O. Owens
Jonathan O. Owens
Reg. No.: 37,902

Attorneys for Applicants

EXPRESS MAIL LABEL NO. EV062940683US

PATENT
Attorney Docket No.: SCI-00100

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

James L. Hobart et al.

Serial No.: 09/018,104

Filed: February 3, 1998

For: **DUAL MODE LASER DELIVERY SYSTEM PROVIDING CONTROLLABLE DEPTH OF TISSUE ABLATION AND CORRESPONDING CONTROLLABLE DEPTH OF COAGULATION**

Group Art Unit: 3739

Examiner: Shay, D.

PRELIMINARY AMENDMENT

162 North Wolfe Road
Sunnyvale, California 94086
(408) 530-9700

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

AMENDMENT

In the Claims:

Please amend the claims as follows (clean version of amended claims)

1. (Four Times Amended) A medical laser delivery apparatus for delivering a series of laser pulses including non-ablative laser pulses to an area of tissue to be treated and generating a region of coagulation to a controllable coagulation depth under a surface of the area of tissue, the apparatus comprising a laser source for generating the series of laser pulses including the non-ablative laser pulses to be delivered to the area of tissue to be treated in order to raise a temperature at the surface of the area of tissue to be treated to a

temperature sufficient to generate coagulation at the coagulation depth when the laser source is in a coagulation mode, wherein the laser source comprises two or more lasers, each for generating laser pulses to provide the series of laser pulses and sufficient to generate ablation when the laser source is in an ablation mode.

2. (Twice Amended) The medical laser delivery apparatus as claimed in claim 1 wherein the series of laser pulses are focussed to the target tissue through an articulated arm feature.

3. (Twice Amended) The medical laser delivery apparatus as claimed in claim 2 wherein the articulated arm feature comprises one or more refocussing optics for refocussing the laser pulses as they travel through the articulated arm feature.

4. (Twice Amended) The medical laser delivery apparatus as claimed in claim 3 wherein the laser delivery system further comprises a scanning handpiece at an end of the articulated arm feature for guiding the series of one or more non-ablative laser pulses to the area of tissue being treated.

11. (Four Times Amended) A medical laser comprising:

a. a laser source having two or more pulsed lasers for generating pulses of laser light, wherein the pulses of laser light are combined in an alternating fashion for generating a laser output having a predetermined absorption, wherein the predetermined absorption forms a predetermined coagulation depth; and

b. a laser control system coupled to the laser source for controlling the laser source to deliver the laser output to a target area.

17. (Four Times Amended) A medical laser delivery apparatus for treating an area of tissue comprising:

a. a laser source having a first laser and a second laser each of which generate laser pulses having a wavelength, the laser source being configured to alternate between laser pulses of the first laser and the second laser to form a single laser output by a combining apparatus for generating a series of laser pulses each having a strength and a duration;

b. a laser delivery system coupled to the laser source for delivering the laser pulses from the laser source to the area of tissue being treated; and

c. a control system coupled to the laser source for controlling generation of the laser pulses from the laser source, wherein the laser source operates in both an ablation mode and a coagulation mode such that when in the ablation mode, the strength and duration of the laser pulses are sufficient to ablate tissue at the area of tissue being treated to a controllable ablation depth and when in the coagulation mode, the strength and duration of the laser pulses are sufficient to generate a coagulation region having a controllable coagulation depth within the tissue remaining at the area of tissue being treated without ablating any tissue.

23. (Four Times Amended) The medical laser delivery apparatus as claimed in claim 22, wherein the first and second lasers are erbium lasers.

41. (Amended) A dual mode medical laser system, for sequentially ablating and coagulating a region of target tissue with ablation laser pulses followed by coagulation laser pulses [to the region of target tissue], the dual mode medical laser system comprising:

a. a laser source comprising a first laser and a second laser for generating a first set of laser pulses and a second set laser pulses;

b. means to alternate between pulses of the first set of laser pulses and the second set of laser pulses to provide a single laser output; and

c. means to direct the single laser output to the region of the target tissue.

Version of Amended Claims with Markings to Show Changes Made:

Please amend Claims 1-4, 11, 17, 23 and 41 as follows

1. (Four Times Amended) A medical laser delivery apparatus for delivering [one or more] a series of laser pulses including non-ablative laser pulses to an area of tissue to be treated and generating a region of coagulation to a controllable coagulation depth under a surface of the area of tissue, the apparatus comprising a laser source for generating [a] the series of [one or more] laser pulses including the non-ablative laser pulses to be delivered to the area of tissue to be treated in order to raise a temperature at the surface of the area of tissue to be treated to a temperature sufficient to generate coagulation at the coagulation depth when the laser source is in a coagulation mode, wherein the laser source comprises two or more lasers, each for generating [two or more corresponding] laser [beams] pulses [which are alternated to produce a single laser output which] to provide[s] the series of [one or more non-ablative] laser pulses and sufficient to generate ablation when the laser source is in an ablation mode.

2. (Twice Amended) The medical laser delivery apparatus as claimed in claim 1 wherein the [single laser output is] series of laser pulses are focussed to the target tissue through an articulated arm feature.

3. (Twice Amended) The medical laser delivery apparatus as claimed in claim 2 wherein the [arm feature is an] articulated arm feature [and] comprises one or more refocussing optics for refocussing the laser pulses as they travel through the articulated arm feature.

4. (Twice Amended) The medical laser delivery apparatus as claimed in claim 3 wherein the laser delivery system further comprises a scanning handpiece at an end of the articulated arm feature for guiding the series of one or more non-ablative laser pulses to the area of tissue being treated.

11. (Four Times Amended) A medical laser comprising:

a. a laser source having two or more pulsed lasers for generating pulses of laser light, wherein the pulses of laser light [which] are combined in an alternating

fashion for generating a laser output having a predetermined absorption, wherein the predetermined absorption forms a predetermined coagulation depth; and

b. a laser control system coupled to the laser source for controlling the laser source [to generate a plurality of coagulative laser pulses from the laser output, such that each such coagulative laser pulse is delivered in sequence] to deliver the laser output to a target area.

17. (Four Times Amended) A medical laser delivery apparatus for treating an area of tissue comprising:

a. a laser source having a first laser and a second laser [two or more lasers] each of which generate laser pulses having a wavelength, [that are combined in an alternating fashion] the laser source being configured to alternate between laser pulses of the first laser and the second laser to form [into] a single laser output by a combining apparatus for generating a series of [one or more] laser pulses each having a strength and a duration;

b. a laser delivery system coupled to the laser source for delivering the laser pulses from the laser source to the area of tissue being treated; and

c. a control system coupled to the laser source for controlling generation of the laser pulses from the laser source, wherein the laser source operates in both an ablation mode and a coagulation mode such that when in the ablation mode, the strength and duration of the laser pulses are sufficient to ablate tissue at the area of tissue being treated to a controllable ablation depth and when in the coagulation mode, the strength and duration of the laser pulses are sufficient to generate a coagulation region having a controllable coagulation depth within the tissue remaining at the area of tissue being treated without ablating any tissue.

23. (Four Times Amended) The medical laser delivery apparatus as claimed in claim 22, wherein the [two or more] first and second lasers are erbium lasers.

41. (Amended) A dual mode medical laser system, for sequentially ablating and coagulating a region of target tissue with ablation laser pulses followed by coagulation laser pulses [to the region of target tissue], the dual mode medical laser system comprising:

a. a laser source comprising a first laser and a second laser for generating a first [laser beam] set of laser pulses and a second [laser beam] set of laser pulses [at a same wavelength];

b. means to alternate between pulses of the first [laser beam] set of laser pulses and the second [laser beam] set of laser pulses to provide a single laser output [to provide the ablation laser pulses and the coagulation laser pulses]; and

c. means to direct the single laser output to the region of the target tissue.

REMARKS

Applicant respectfully requests further examination and reconsideration in view of the above amendments and arguments set forth fully below. Claims 1-14, 17-24 and 41-49 were previously pending in the instant application. Within the previous Office Action, Claims 1-14, 17-24 and 41-49 have been rejected. By way of the above amendment, Claims 1-4, 11, 17, 23 and 41 have been amended. Claims 1-14, 17-24 and 41-49 are still pending in this application.

Rejections Under 35 U.S.C. § 112

Claims 41-49 have been rejected under 35 U.S.C. 112, first paragraph, for containing subject matter which was not described in the specification in such a way as to convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Within the Office Action it is specifically stated that the originally filed disclosure is silent on the lasers producing the same wavelength. For all the reasons discussed in the response to the previous Office Action, the Applicants respectfully disagree. However, in order to further the prosecution of this Application, Claim 41 has been amended to remove the recitation of "a same wavelength." Claims 42-49 are dependent on the independent claim 42.

Claims 2-5, 11-14, 17-23 and 49 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Within the Office Action it is specifically stated that is not clear in Claims 2 and 49 what is meant by "arm feature." Claim 2 has been amended, as suggested within the Office Action, to recite "an articulated arm feature." Claim 49 already recited "an articulated arm feature."

Regarding Claims 11 and 17 it is stated within the Office Action that it is unclear what is meant by two or more lasers combined in an alternating pattern or fashion to produce a plurality of coagulative laser pulses." Claim 11 has been amended to recite a laser source having two or more pulsed lasers for generating pulses of laser light, wherein the pulses of laser light are combined in an alternating fashion for generating a laser output having a predetermined absorption, wherein the predetermined absorption forms a predetermined coagulation depth. Claim 17 has been amended to recite a laser source having a first laser and a second laser each of which generate laser pulses having a wavelength, the laser source being configured to alternate between laser pulses of the first laser and the second laser to form a single laser output by a

combining apparatus for generating a series of one or more laser pulses each having a strength and a duration. Thus, in Claims 11 and 17 it is abundantly clear that the laser output comprises pulsed laser light from each of the lasers. Claims 12-14 depend on the independent Claim 11, and Claims 18-23 dependent on the independent Claim 16.

Rejections Under 35 U.S.C. § 102

Within the previous Office Action, Claims 1, 2, 11 and 17 have been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,125,922 to Dwyer (hereafter "Dwyer"). The Applicants respectfully traverse this rejection. No description to the teachings of Dwyer or detailed reasons for the rejection is given within the Office Action.

Dwyer teaches a laser device that switches between a first laser beam with a first set of laser conditions and a second laser beam with a second set of laser conditions. Dwyer teaches that by manipulating the optics within the cavity of a Nd:YAG laser, the most probable lasing transition producing laser light 1.06 microns, can effectively be shut off such that lasing can occur to produce laser light at 1.3 microns. [Dwyer, Abstract] In other words, Dwyer teaches a laser device with a tunable laser cavity for switching between two lasing conditions and thus producing two wavelengths, only one of which is generated under any one set of laser conditions.

Dwyer also teaches that a system can have two lasers with one of the lasers operating at 1.06 microns and the other laser operating at 1.3 microns, such that a surgeon can switch between the two lasers for cauterizing and cutting, respectively. However, Dwyer does not teach using one or more pulsed lasers, wherein pulses from each of the pulsed lasers are combined into a single laser output to produce conditions for non-ablation or coagulation. In fact Dwyer does not teach combining laser light from multiple lasers at all.

In contrast to the teachings of Dwyer, the instant invention is directed to a laser system that is capable of operating in an ablation mode and a coagulation mode by using two or more pulsed laser sources, wherein pulses from each of the laser sources are combined to deliver a series of laser pulses for ablating tissue or coagulating tissue. Each of the independent Claims 1, 11, 17 and 41 recite the features of combining laser pulses from two or more laser sources.

Specifically, the independent Claim 1 is directed to medical laser delivery apparatus for delivering a series of laser pulses including non-ablative laser pulses to an area of tissue to be treated and generating a region of coagulation to a controllable coagulation depth under a surface of the area of tissue, the apparatus comprising a laser source for generating the series of laser pulses including the non-ablative laser pulses to be delivered to the area of tissue to be treated in

order to raise a temperature at the surface of the area of tissue to be treated to a temperature sufficient to generate coagulation at the coagulation depth when the laser source is in a coagulation mode , wherein the laser source comprises two or more lasers, each for generating laser pulses to provide the series of laser pulses and sufficient to generate ablation when the laser source is in an ablation mode. As discussed above, Dwyer does not teach or suggest a medical laser for delivering a series of laser pulses comprising combined laser pulses from two or more lasers. For at least these reasons, the independent Claim 1 is allowable over the teachings Dwyer.

Claim 2 is dependent on the independent Claim 1. As described above, the independent Claim 1 is allowable over the teachings of Dwyer. Accordingly, Claim 2 is also allowable as being dependent upon an allowable base claim.

The independent Claim 11 is directed to a medical laser comprising a laser source having two or more pulsed lasers for generating pluses of laser light, wherein the pulses of laser light are combined in an alternating fashion for generating a laser output having a predetermined absorption, wherein the predetermined absorption forms a predetermined coagulation depth and a laser control system coupled to the laser source for controlling the laser source to deliver the laser output to a target area. As discussed above, Dwyer does not teach or suggest a medical laser with a laser source having two or more pulsed lasers for generating pluses of laser light, wherein the pulses of laser light are combined in an alternating fashion for generating a laser output having a predetermined absorption, wherein the predetermined absorption forms a predetermined coagulation depth. For at least these reasons, the independent Claim 11 is allowable over the teachings of Dwyer.

The independent Claim 17 is directed to a medical laser delivery apparatus for treating an area of tissue comprising a laser source having a first laser and a second laser each of which generate laser pulses having a wavelength, the laser source being configured to alternate between laser pulses of the first laser and the second laser to form a single laser output by a combining apparatus for generating a series of one or more laser pulses each having a strength and a duration, a laser delivery system coupled to the laser source for delivering the laser pulses from the laser source to the area of tissue being treated and a control system coupled to the laser source for controlling generation of the laser pulses from the laser source, wherein the laser source operates in both an ablation mode and a coagulation mode such that when in the ablation mode, the strength and duration of the laser pulses are sufficient to ablate tissue at the area of tissue being treated to a controllable ablation depth and when in the coagulation mode, the strength and

duration of the laser pulses are sufficient to generate a coagulation region having a controllable coagulation depth within the tissue remaining at the area of tissue being treated without ablating any tissue. As discussed above, Dwyer does not teach or suggest a medical laser delivery apparatus with a laser source having a first laser and a second laser each of which generate laser pulses having a wavelength, the laser source being configured to alternate between laser pulses of the first laser and the second laser to form a single laser output by a combining apparatus for generating a series of one or more laser pulses each having a strength and a duration. For at least these reasons, the independent Claim 17 is allowable over the teachings of Dwyer.

Rejections Under 35 U.S.C. § 103

Within the previous Office Action, Claims 1-3, 6-8, 11-14, 17-19 and 43-49 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,098,426 to Sklar et al. (hereinafter "Sklar") in combination with U.S. Patent No. 4,672,969 to Dew (hereinafter "Dew"), U.S. Patent No. 5,620,435 to Belkin et al. (hereinafter "Belkin"), Dwyer and the article entitled "Selective Photothermolysis: Precise Microsurgery by Selective Absorption of Pulsed Radiation" by R. Rox Anderson and John A. Parrish (hereinafter "Anderson").

The teachings of Sklar are applied as the primary reference in a U.S.C. 103(a) rejection of Claims 1-3, 6-8, 11-14, 17-19 and 43-49 in the instant application. The teachings of Sklar have been fully characterized in previous communications. Briefly, the teachings of Sklar are directed to a system and method for accurately controlling and positioning laser sources, specifically during surgery. According to Sklar "a limiting factor to the duration of the operation under these procedures (viz. Prior Art procedures) is the surgeon's reaction time while focusing on the target and the patients movement while the surgeon is trying to find the target and react to the target recognition by firing the laser. [Sklar, column 5, lines 13-19] In view of these prior art limitations, Sklar teaches a system for performing precision laser surgery which includes an imaging system for providing a surgeon with precision tracking and topographical information regarding the surgical target area. [Sklar, Abstract] Sklar states that it is well appreciated that the limitations on the achievable accuracy and control of laser surgical instruments today is no longer paced by the development of laser technology, but by the imaging and tracking technologies needed to efficiently use the laser. [Sklar, column 2, lines 39-43]

Sklar does not teach a laser device, or a laser system, with a laser source having two or more pulsed lasers, wherein pulses from the two or more pulsed lasers are alternated and combined to generate a single laser output as currently recited in each of the Independent Claims

1, 11 and 17. Nor does Sklar teach a laser device, or a laser system, for generating both ablation and coagulation laser pulses as recited in Independent Claim 41. Further, Sklar does not teach an articulated arm structure for guiding the single laser output, as recited in Claims 3, 14 and 49, or a plurality of refocussing lenses for focussing the single laser output, as recited in claims 5, 14 and 49.

Dew teaches a laser healing method to effect wound closure and reconstruction of biological tissue. Optical energy is applied to produce thermal heating of biological tissue to a degree suitable for denaturing the tissue proteins such that the collagenous elements of the tissue form a biological glue to seal and reconstruct the tissue being heated. [Dew, Abstract] The system of Dew includes a laser 20. Dew teaches a marker laser 30 which is coaligned with the infrared beam of the laser 20. Dew teaches that an auxiliary source of optical energy 50 can be incorporated into the apparatus to emit radiation having a wavelength which is intensely absorbed by biological tissue.

Dew does not teach a laser source with two or more lasers that produce laser beams that are alternated and combined to generate a single laser output as currently recited in each of the Independent Claims 1, 11 and 17 or for generating both ablation and coagulation laser pulses as recited in Independent Claim 41. Further, Dew does not teach an articulated arm for guiding the single laser output, as recited in Claims 3, 14 and 49, or a plurality of refocussing lenses for focussing the single laser output, as recited in claims 5, 14 and 49. Nor does Dew teach a user interface, the elements of which are recited in claims 7, 12, and 44-46.

Belkin teaches a method for welding ocular tissues to each other using a carbon dioxide laser. [Belkin, col. 2, lines 35-44] Belkin does not teach a medical laser with a laser source with two or more pulsed, wherein pulses from each of the lasers are combined from generating a series of laser pulses as currently recited the independent Claims 1, 11 and 17 or for generating both ablation and coagulation laser pulses as recited in Independent Claim 41. Further, Belkin does not teach an articulated arm structure for guiding the single laser output, as recited in Claims 3, 14 and 49, or a plurality of refocussing lenses for focussing the single laser output, as recited in claims 5, 14 and 49. Nor does Belkin teach a user interface, the elements of which are recited in claims 7, 12, and 44-46.

Anderson teaches a scheme for confining thermally mediated radiation damage to chosen pigmented targets. [Anderson, p. 524] The technique relies on selective absorption of a brief radiation pulse to generate and confine heat at certain pigmented targets. [Anderson, p. 524] Anderson does not teach a medical laser with a laser system as currently claimed. Specifically,

Anderson does not teach laser source with two or more lasers that produce pulses which are alternated or combined to generate a single laser output as currently recited in each of the Independent Claims 1, 11 and 17, or for generating both ablation and coagulation laser pulses as recited in Independent Claim 41. Further, Anderson does not teach an articulated arm for guiding the single laser output, as recited in Claims 3, 14 and 49, or a plurality of refocussing lenses for focussing the single laser output, as recited in claims 5, 14 and 49. Nor does Anderson teach a user interface, the elements of which are recited in claims 7, 12, and 44-46.

In contrast to the teachings of Sklar, Dew, Anderson, Belkin and Dwyer, the current invention is a laser system that utilizes multiple lasers. The lasers are preferably pulsed lasers. The pulses from the lasers are alternated or combined into a single laser output or series of pulses with a galvanometer or other suitable device to selectively generate the conditions for ablation or coagulation. The single laser output is preferably guided to a target tissue through an articulated arm with a series of refocussing optics. The system preferably has a user interface that allows a user to select laser pulse patterns, target sizes and operating modes. The interface preferably is a graphical user interface that displays the selected laser pulse pattern and allows the user to select a desired ablation depth value and coagulation depth value. The combinations of features claimed in the instant application are neither taught or suggested by Sklar, Dew, Belkin, Anderson nor their combination.

The independent Claim 1 is directed to medical laser delivery apparatus for delivering a series of laser pulses including non-ablative laser pulses to an area of tissue to be treated and generating a region of coagulation to a controllable coagulation depth under a surface of the area of tissue, the apparatus comprising a laser source for generating the series of laser pulses including the non-ablative laser pulses to be delivered to the area of tissue to be treated in order to raise a temperature at the surface of the area of tissue to be treated to a temperature sufficient to generate coagulation at the coagulation depth when the laser source is in a coagulation mode, wherein the laser source comprises two or more lasers, each for generating laser pulses to provide the series of laser pulses and sufficient to generate ablation when the laser source is in an ablation mode. As discussed above, neither Sklar, Dew, Belkin, Anderson, Dwyer nor their combination teach a medical laser for delivering a series of laser pulses comprising combined laser pulses from two or more lasers. For at least these reasons, the independent Claim 1 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination.

Claims 2, 3 and 6-8 are all dependent on the independent Claim 1. As described above, the independent Claim 1 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer

and their combination. Accordingly, Claims 2, 3 and 6-8 are all also allowable as being dependent upon an allowable base claim.

The independent Claim 11 is directed to a medical laser comprising a laser source having two or more pulsed lasers for generating pluses of laser light, wherein the pulses of laser light are combined in an alternating fashion for generating a laser output having a predetermined absorption, wherein the predetermined absorption forms a predetermined coagulation depth and a laser control system coupled to the laser source for controlling the laser source to deliver the laser output to a target area. As discussed above, neither Sklar, Dew, Belkin, Anderson, Dwyer nor their combination teach a medical laser with a laser source having two or more pulsed lasers for generating pulses of laser light, wherein the pulses of laser light are combined in an alternating fashion for generating a laser output having a predetermined absorption, wherein the predetermined absorption forms a predetermined coagulation depth. For at least these reasons, the independent Claim 11 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination.

Claims 12-14 are all dependent on the independent Claim 11. As described above, the independent Claim 11 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination. Accordingly, Claims 12-14 are all also allowable as being dependent upon an allowable base claim.

The independent Claim 17 is medical laser delivery apparatus for treating an area of tissue comprising a laser source having a first laser and a second laser each of which generate laser pulses having a wavelength, the laser source being configured to alternate between laser pulses of the first laser and the second laser to form a single laser output by a combining apparatus for generating a series of laser pulses each having a strength and a duration, a laser delivery system coupled to the laser source for delivering the laser pulses from the laser source to the area of tissue being treated and a control system coupled to the laser source for controlling generation of the laser pulses from the laser source, wherein the laser source operates in both an ablation mode and a coagulation mode such that when in the ablation mode, the strength and duration of the laser pulses are sufficient to ablate tissue at the area of tissue being treated to a controllable ablation depth and when in the coagulation mode, the strength and duration of the laser pulses are sufficient to generate a coagulation region having a controllable coagulation depth within the tissue remaining at the area of tissue being treated without ablating any tissue. As discussed above, neither Sklar, Dew, Belkin, Anderson, Dwyer nor their combination teach a medical laser delivery apparatus which has two or more lasers which are combined in an

alternating fashion into a single laser output and a control system coupled for controlling the laser source for generating laser pulses with the strength and duration for both ablation and coagulation. For at least these reasons, the independent Claim 17 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination.

Claims 18 and 19 are both dependent on the independent Claim 17. As described above, the independent Claim 17 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination. Accordingly, Claims 18 and 19 are both allowable as being dependent upon an allowable base claim.

The independent Claim 41 is directed to a dual mode medical laser system, for sequentially ablating and coagulating a region of target tissue with ablation laser pulses followed by coagulation laser pulses, the dual mode medical laser system comprising a laser source comprising a first laser and a second laser for generating a first set of laser pulses and a second set laser pulses, means to alternate between pulses of the first set of laser pulses and the second set of laser pulses to provide a single laser output and means to direct the single laser output to the region of the target tissue. As discussed above, neither Sklar, Dew, Belkin, Anderson. Dwyer nor their combination teach a medical laser delivery apparatus having first laser and a second laser for generating a first set of laser pulses and a second set laser pulses alternate to provide a single laser output. For at least these reasons, the new independent Claim 41 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination.

Claims 42-49 all dependent on the independent Claim 41. As described above, the independent Claim 41 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination. Accordingly, Claims 42-49 are all allowable as being dependent upon an allowable base claim.

Within the Office Action, Claims 4, 5, 9, 10, 20-24 and 42 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Sklar in combination with Dew, Anderson, Belkin and Dwyer, and further in view of U.S. Patent No. 5,938,657 to Assa et al. (hereinafter "Assa"). Assa teaches an apparatus for delivering energy with a continuous output.

Claims 4, 5, 9 and 10 are all dependent on the independent Claim 1. As described above, the independent Claim 1 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination. Accordingly, Claims 4, 5, 9 and 10 are all also allowable as being dependent upon an allowable base claim.

Claims 20-24 are all dependent on the independent Claim 17. As described above, the independent Claim 17 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer

and their combination. Accordingly, Claims 20-24 are all also allowable as being dependent upon an allowable base claim.

Claim 42 is dependent on the independent Claim 41. As described above, the independent Claim 41 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination. Accordingly, Claim 42 is also allowable as being dependent upon an allowable base claim.

For the reasons given above, Applicants respectfully submit that the claims are in a condition for allowance, and allowance at an early date would be appreciated. Should the Examiner have any questions or comments, they are encouraged to call the undersigned at (408) 530-9700 to discuss the same so that any outstanding issues can be expeditiously resolved.

Respectfully submitted,
HAVERSTOCK & OWENS LLP

Dated: September 30, 2002 By: _____

Jonathan O. Owens
Reg. No.: 37,902

Attorneys for Applicant

PATENT
Attorney Docket No.: SCI-00100

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Group Art Unit: 3739
	Examiner: Shay, David M.
James L. Hobart *et al.*	
	REQUEST FOR A THREE MONTH EXTENSION OF TIME
Serial No.: 09/018,104	
Filed: February 3, 1998	162 North Wolfe Road Sunnyvale, CA 94086 (408)530-9700 Customer Number 28960
For: **DUAL MODE LASER DELIVERY SYSTEM PROVIDING CONTROLLABLE DEPTH OF TISSUE ABLATION AND CORRESPONDING CONTROLLABLE DEPTH OF COAGULATION**	

Mail Stop: RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants hereby petition for a three months extension of time to answer the outstanding office action mailed May 14, 2004 regarding the above-identified patent application. Please find a check enclosed in the amount of $885.00 ($490.00 to cover the three months extention of time filing fee plus $395.00 for the request for examination filing fee) enclosed.

Respectfully submitted,
HAVERSTOCK & OWENS LLP

Dated: November 12, 2004

By: Jonathan O. Owens
Reg. No.: 37,902

Attorneys for Applicants

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the U.S. Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the: Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450

HAVERSTOCK & OWENS LLP
11/12/04

Attorney Docket No.: SCI-00100

HAVERSTOCK & OWENS LLP
162 North Wolfe Road
Sunnyvale, California 94086
(408) 530-9700
Customer No.: 28960

In re Application of: James L. Hobart et al.
Serial No.: 09/018,104
Filed: February 3, 1998
Entitled: DUAL MODE LASER DELIVERY SYSTEM PROVIDING CONTROLLABLE DEPTH OF TISSUE ABLATION AND CORRESPONDING CONTROLLABLE DEPTH OF COAGULATION
Group Art Unit: 3739
Examiner Name: Shay, David M.

MAIL STOP RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REQUEST FOR CONTINUED EXAMINATION (RCE) TRANSMITTAL

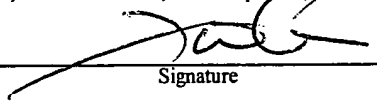
Sir:

This is a Request for a Continued Examination (RCE) under 37 CFR § 1.114 of the above-identified application.

CERTIFICATION UNDER 37 CFR § 1.08

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to : Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, Mail Stop RCE, November 12, 2004.

Francis Guerra
(Name of Person Mailing Paper)



Signature

1. **Submission required under C.F.R. § 1.114**

a. X Previously submitted

i. X Consider the amendment(s)/reply under 37 C.F.R. § 1.116 previously filed on July 14, 2004. (Any unentered amendment(s) referred to above will be entered)

ii. _____ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____.

iii. _____ Other _____.

b. X Enclosed

i. _____ Amendment/Reply

ii _____ Affidavit(s)/Declaration(s)

iii. _____ Information Disclosure Statement (IDS)

iv. X Other Request for Three Months Extension of Time

2. **Miscellaneous**

a. _____ Suspension of action on the above-identified application is requested under 37 C.F.R. § 1.103(c) for a period of _____ months.
(Period of suspension shall not exceed 3 months; Fee under 37 C.F.R. § 1.17(i) required)

b. _____ Other _____.

3. c. X Applicant is entitled to small entity status

4. **Fees** The RCE fee under 37 C.F.R. § 1.17(e) is required by 37C.F.R. § 1.114 when the RCE is filed.

a. X The Director is hereby authorized to charge the following fees, or credit any overpayments to Deposit Account No.: 08-1275

i. X RCE fee required under 37 C.F.R. § 1.17(e)

ii. X Extension of time fee (37 C.F. R. § § 1.136 and 1.17)

iii. _____ Other _____

b. X Check in the amount of $885.00 ($395.00 to cover the Request for Continued Examination Filing fee plus $490.00 for a three months extension of time fee) enclosed

c. _____ Payment by credit card (form PTO-2038 enclosed)

5. X Return Receipt Postcard

Dated: November 12, 2004

By: Jonathan O. Owens
Name: Jonathan O. Owens
Registration No.: 37,902

Attorney Docket No.: SCI-00100

HAVERSTOCK & OWENS LLP
162 North Wolfe Road
Sunnyvale, California 94086
(408) 530-9700
Customer No.: 28960

In re Application of: James L. Hobart et al.
Serial No.: 09/018,104
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Group Art Unit: 3739
Examiner Name: Shay, David M.

MAIL STOP RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REQUEST FOR CONTINUED EXAMINATION (RCE) TRANSMITTAL

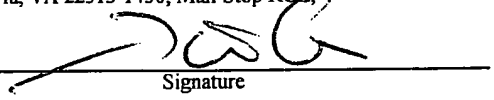
Sir:

This is a Request for a Continued Examination (RCE) under 37 CFR § 1.114 of the above-identified application.

CERTIFICATION UNDER 37 CFR § 1.08

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to : Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, Mail Stop RCE, on November 12, 2004.

Francis Guerra
(Name of Person Mailing Paper)


Signature

1. **Submission required under C.F.R. § 1.114**

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i. X Consider the amendment(s)/reply under 37 C.F.R. § 1.116 previously filed on July 14, 2004. (Any unentered amendment(s) referred to above will be entered)

ii. _____ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____.

iii. _____ Other _____.

b. X Enclosed

i. _____ Amendment/Reply

ii _____ Affidavit(s)/Declaration(s)

iii. _____ Information Disclosure Statement (IDS)

iv. X Other Request for Three Months Extension of Time

2. **Miscellaneous**

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(Period of suspension shall not exceed 3 months; Fee under 37 C.F.R. § 1.17(i) required)

b. _____ Other _____.

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4. **Fees** The RCE fee under 37 C.F.R. § 1.17(e) is required by 37C.F.R. § 1.114 when the RCE is filed.

a. X The Director is hereby authorized to charge the following fees, or credit any overpayments to Deposit Account No.: 08-1275

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c. _____ Payment by credit card (form PTO-2038 enclosed)

5. X Return Receipt Postcard

Dated: November 12, 2004

By: _____
Name: Jonathan O. Owens
Registration No.: 37,902

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/018,104	02/03/1998	JAMES L. HOBART	PHAN-00100	9278

28960 7590 04/07/2005

HAVERSTOCK & OWENS LLP
162 NORTH WOLFE ROAD
SUNNYVALE, CA 94086

EXAMINER	
SHAY, DAVID M	

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/018,104	HOBART ET AL.	
	Examiner	Art Unit	
	david shay	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *November 15, 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14,17-24 and 41-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14, 17-24, and 41-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date May 13, 2002
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 19, 2004 has been entered.

Applicant argues that with the device of Dwyer it is "not feasible to alternate between pulse or sets of pulses in the time frame required to perform coagulation o ablation on a target area tissues as recited in the claim". The examiner must, respectfully disagree. Dwyer et al specifically teach that the device can both cut (ablate) and coagulate, and that the switching between the two functions can be done quickly (see column 3, lines 51-55).

Applicant continues arguing that claim 1 requires an apparatus "for delivering a series of laser pulses having a wavelength, the medical laser delivery apparatus" (emphasis in original) with a non-ablative laser pulse for coagulating to a controllable depth. The examiner first notes that comprising-type claim language allows for more than one wavelength to exist in the laser output even if a series of the pulses is at "a wavelength". Applicant is also respectfully reminded that the originally filed disclosure does not provide support for both laser sources producing pulses of the same wavelength (see the office actions mailed March 26, 2001 and September 17, 2001). With regard to the controllable coagulation depth, the examiner notes that the controllability of the coagulation depth is a provided buy controlling the exposure time of the tissue (see instant disclosure, the paragraph bridging pages 4 and 5), thus the exposure control of Dwyer et al, allowing the laser to be turned on and off "as desired" provides the claimed

controllability, thus claim 1, which recites no specific time frame, still clearly anticipates claim 1 as amended. These comments also apply to amended claims 11 and 41.

Regarding the combination rejection, applicant argues that the references combined with Dwyer et al have been characterized previously and argues the allowability of all dependent claims flows from the allowability of their independent claims. The examiner firstly note that as claims 1, 11 and 41 are, in fact, not patentable over Dwyer et al, the dependant claims are similarly unpatentable over the combination as set forth more fully in previous rejections.

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claim 5 has been renumbered 52.The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 11 and 41 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Dwyer et al.

Claims 1-3, 8, 41, 43, 44 and 47-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dew ('969) in combination with Anderson et al, and Belkin et al. Dew ('969) teaches the use of a carbon dioxide laser operating at 10.6 microns as a cutting laser in a laser system comprised of multiple lasers and teaches that the power of a pulse determines the amount of heat deposited in the tissue and that the same type of laser can be used for cutting and coagulating. Belkin et al teach that the carbon dioxide lasers operating at 10.6 microns can be

used to heat rather than cut tissue. Anderson et al teach the way parameters such as absorptivity, spot size, and pulse width interrelate to control the amount of energy absorbed by tissue. It would have been obvious to the artisan of ordinary skill to use a carbon dioxide laser to coagulate in the device of Dew ('969), since this laser can be configured to coagulate as taught by Belkin et al, and since this would render the device more versatile, at no extra cost; and to employ the particular laser parameters claimed since these provide no unexpected results, and are within the scope of one having ordinary skill in the art as shown by Anderson et al; to employ an articulated arm with refocusing convex lenses since these are notorious in the art for transporting infrared radiation such as that from Carbon dioxide lasers, official notice of which has already taken; and to use a galvanometer to alternate the beams, since these are notorious for moving optical components official notice which has already been taken thus producing a device such as claimed.

Claims 1,6, 7, 11-13, 17, 18, 41 and 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sklar et al in combination with Dwyer et al. Sklar et al teach the use of a graphic user interface for use with multiple lasers and teach that it can be used with any type of laser for any type of surgery and that the depth of laser action; energy per pulse; and repetition rate can be input and displayed. Dwyer et al provide a dual laser system with controllable spot size. It would have been obvious to the artisan of ordinary skill to employ the interface of Sklar et al in the device of Dwyer et al, since Dwyer et al provide no control interface for the device made up of two separate lasers or to employ the dual laser source of Dwyer et al in the system of Sklar et al, since Sklar et al provide no particular laser source, thus producing a device such as claimed.

Claims 4, 9, 10, 42 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dew ('969) in combination with Anderson et al and Belkin et al as applied to claims 1-3, 8, 41, 43, 44, and 47-49 are above, and further in combination with Assa et al. Assa et al teach a scanning hand piece and the equivalence of carbon dioxide and Erbium YAG lasers. Thus it would have been obvious to the artisan or ordinary skill to employ a scanning hand piece as taught by Assa et al, since his allows more consistency of treatment and to employ an erbium laser, since these are equivalent to the carbon dioxide laser, thus producing a device such as claimed.

Claims 14 and 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dew ('969) in combination with Anderson et al and Belkin et al as applied to claims 1-3, 8, 41, 43, 44 and 47-49 above, and further in combination with Sklar et al. Sklar et al teach a user interface for a multi-laser system. It would have been obvious to the artisan of ordinary skill to employ the interface of Sklar et al, since no interface is taught and this would allow the surgical treatment to be preprogrammed, as taught by Sklar et al, thus producing a device such as claimed.

Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dew ('969) in combination with Anderson et al, Belkin et al, and Sklar et al as applied to claim 14 and 19-22 above, and further in combination with Assa et al. The teachings of Assa et al and the motivations for combination thereof are essentially those already iterated above. Thus it would have been obvious to the artisan of ordinary skill to combine those old and well known teachings to produce a device such as claimed.

Applicant's arguments filed July 19, 2004 have been fully considered but they are not persuasive. The arguments are not convincing for the reasons set forth above.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to David Shay at telephone number (571) 272-4773.

DAVID M. SHAY
PRIMARY EXAMINER
GROUP 330

FORM PTO-1449 (Modified)

U.S. Department of Commerce Patent and Trademark Office

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Several Sheets if Necessary)

(37 CFR § 1.98(b))

Attorney Docket No. [redacted]-00100 | Serial No.: 09/018,104

Applicant: James L. Hobart et al.

Filing Date: February 3, 1998 | Group Art Unit: 3739

U.S. PATENT DOCUMENTS

Examiner Initials		Serial / Patent Number	Issue Date	Applicant / Patentee	Class	Subclass	Filing Date
	CS	5,190,032	03/02/93	Zacoi	128	400	02/03/92
	CT	5,198,926	03/30/93	Sheinis et al.	359	356	01/18/91
	CU	5,207,576	05/04/93	Vassiliadis et al.	433	215	04/25/89
	CV	5,210,398	05/11/93	Metlitsky	235	462	06/14/91
	CW	5,226,907	07/13/93	Tankovich	606	133	10/29/91
	CX	5,227,910	07/13/93	Khattak	359	211	03/27/92
	CY	5,275,564	01/04/94	Vassiliadis et al.	433	226	02/12/92
	CZ	5,282,797	02/01/94	Chess	606	9	05/28/91
	DA	5,292,320	03/08/94	Brown et al.	606	15	07/06/92
	DB	5,344,418	09/06/94	Gharffari	606	9	12/12/91
	DC	5,359,669	10/25/94	Shanley et al.	382	6	04/13/92
	DD	5,360,447	11/01/94	Koop	623	15	02/03/93
	DE	5,411,502	05/02/95	Zair	606	10	12/30/93
	DF	5,413,555	05/09/95	McMahan	606	4	04/30/93
	DG	5,421,819	06/06/95	Edwards et al.	604	22	05/13/93
	DH	5,423,801	06/13/95	Marshall et al.	606	5	12/19/91
	DI	5,425,727	06/20/95	Koziol	606	5	10/07/93
	DJ	5,425,728	06/20/95	Tanovich	606	9	01/19/93
	DK	5,426,662	06/20/95	Mefferd et al.	372	99	04/28/94
	DL	5,464,013	11/07/95	Lemelson	128	633.01	11/23/91
	DM	5,480,396	01/02/96	Simon et al.	606	4	12/09/94
	DN	5,486,172	01/23/96	Chess	606	20	01/31/94
	DO	5,520,679	05/28/96	Lin	600	5	03/23/94
	DP	5,531,740	07/02/96	Black	606	9	09/06/94
	DQ	5,546,214	08/13/96	Black et al.	359	203	09/13/95
	DR	5,582,752	12/10/96	Zair	219	121.85	12/19/94
	DS	5,595,568	01/21/97	Anderson et al.	606	9	02/01/95
	DT	5,611,795	03/18/97	Slatkine et al.	606	9	02/03/95
	DU	5,624,437	04/29/97	Freeman et al.	606	12	03/28/95
	DV	5,637,850	06/10/97	Honda	235	454	12/27/95
	DW	5,642,287	06/24/97	Sotiropoulos et al.	364	474.08	03/02/95
	DX	5,645,550	07/08/97	Hohla	606	108	04/08/94
	DY	5,651,784	07/29/97	Klopotek	606	5	12/28/94
	DZ	5,735,844	04/07/98	Anderson et al.	606	9	01/30/96
	EA	5,756,981	05/26/98	Roustaei et al.	235	462	08/01/96
	EB	5,769,787	06/23/98	Lemelson	600	407	06/07/95
	EC	5,770,847	06/23/98	Olmstead	235	46.2	12/23/94

Examiner: [signature] | Date Considered: February 25, 2005

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No.: SCI-00100	Serial No.: 09/018,104
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use Several Sheets If Necessary)		Applicant: James L. Hobart et al.	RECEIVED
(37 CFR § 1.98(b))		Filing Date: February 3, 1998	Group Art Unit: 3739

U.S. PATENT DOCUMENTS

Examiner Initials		Serial / Patent Number	Issue Date	Applicant / Patentee	Class	Subclass	Filing Date
	ED	5,782,822	07/21/98	Telfair et al.	~~606~~	~~5~~	10/27/95
	EE	5,783,798	07/21/98	Abraham	~~219~~	~~121.73~~	12/19/95
	EF	5,814,803	09/29/98	Olmstead et al.	~~235~~	~~462~~	12/21/95
	EG	5,814,827	09/29/98	Katz	~~250~~	~~556~~	05/05/97
	EH	5,846,080	12/08/98	Schneider	~~433~~	~~215~~	12/20/95
	EI	5,849,006	12/15/98	Frey et al.	~~606~~	~~5~~	04/25/94
	EJ	5,865,830	02/02/99	Parel et al.	~~606~~	~~5~~	06/06/95
	EK	5,868,731	02/09/99	Budnik et al.	~~606~~	~~9~~	03/04/96
	EL	5,883,658	03/16/99	Schubert et al.	~~347~~	~~258~~	09/29/97
	EM	5,900,963	05/04/99	Li et al.	~~359~~	~~205~~	09/29/97
	EN	5,931,848	08/03/99	Saadat	~~606~~	167	05/27/97
	EO	5,933,268	08/03/99	Li et al.	~~359~~	~~207~~	09/29/97
	EP	5,941,893	08/24/99	Saadat	~~606~~	~~180~~	05/27/97
	EQ	5,997,531	12/07/99	Loeb et al.	~~606~~	~~13~~	01/29/98
	ER	6,066,127	05/23/00	Abe	~~606~~	~~2~~	09/21/98
	ES	6,228,075 B1	05/08/01	Furumoto	~~606~~	~~9~~	03/15/99
	ET	6,228,076 B1	05/08/01	Winston et al.	~~606~~	~~11~~	01/09/99
	EU	6,267,771 B1	07/31/01	Tanovich et al.	~~606~~	131	02/27/96
	EW						
	EX						
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	FA						
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	FG						
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	FI						
	FJ						
	FK						

Examiner: [signature] Date Considered: February 15, 2005

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 Commerce (Modified)	U.S. Department of Patent and Trademark Office	Attorney Docket No.: SCI-00100	Serial No.: 09/018,104
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use Several Sheets If Necessary)		Applicant: James L. Hobart et al.	
(37 CFR § 1.98(b))		Filing Date: February 3, 1998	Group Art Unit: 3739

FOREIGN PATENTS OR PUBLISHED FOREIGN PATENT APPLICATIONS

		Document Number	Publication Date	Country / Patent Office	Class	Subclass	Translation Yes/	Translation No
	FL	EP 0 073 617 A1	03/09/83	EP	~~A 61 C~~			X
	FM	EP 0 714 642 A1	06/05/96	EP	~~A 61 F~~	~~2/10~~		X
	FN	JP 56-166123	12/21/81	JP	~~A 61 K~~	~~45/00~~		X
	FO	WO 86/02783	05/09/86	PCT	~~H 01 S~~	~~3/08~~		X
	FP	WO 93/03521	02/18/83	PCT	~~H01S~~	~~3/08~~		X
	FQ	WO 95/15725	06/15/95	PCT	~~A61B~~	~~17/41~~		X

OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)

	FR	Brigitte Dreno, MD., et al., "The Benefit of Chilling in Argon-Laser Treatment of Port-Wine Stains," Vol. 75, No. 1, Chilling in Argon-Laser Treatment, pp. 42-45.
	FS	Barbara A. Gilchrest.et al., "Chilling Port Wine Stains Improves the Response to Argon Laser Therapy," Plastic and Reconstructive Surgery, Vol. 69, No. 2, 1982, pp. 278-283.
	FT	Akira Yanai, M.D., et al., "Argon Laser Therapy of Port-Wine Stains: Effects and Limitations," Vol. 75, No. 4, April 1985, pp. 520-525.
	FU	Leon Goldman, MD., et al., "Replica Microscopy and Scanning Electron Microscopy of Laser Impacts on the Skin," The Journal of Investigative Dermatology, Vol. 52, No. 1, pp. 18-24.
	FV	Melanie C. Grossman M.D., et al., "Damage to hair follicles by normal-mode ruby laser pulses," Journal of the American Academy of Dermatology, December 1996, pp. 889-894.
	FW	Luigi L. Polla MD., et al., "Melanosomes Are a Primary Target of Q-Switched Ruby Laser Irradiation in Guinea Pig Skin," The Society for Investigative Dermatology, Inc., Vol. 89, No. 3, 1987, pp. 281-286.
	FX	"The Journal of Investigate Dermatology," April 1987, Vol. 88, No. 4, pp. 523.
	FY	M. Douglas Gossman, MD., et al., "Prospective Evaluation of the Argon Laser in the Treatment of Trichiasis," March 1992, Vol. 23, No. 3, 183-187.
	FZ	R. Rox Anderson et al., "The Optics of Human Skin," The Journal of Investigative Dermatology 77, 1981, pp. 13-19.
	GA	Leon Goldman M.D., et al., "Treatment of Basal Cell Epithelioma by Laser Radiation," Epithelioma-Goldman & Wilson, 1961, Vol. 189, No. 10, pp. 773-775.
	GB	Leon Goldman MD., et al., "Laser Action at the Cellular Level," Multidiscipline Research Forum, JAMA, Nov. 7, 1996, Vol. 198, No. 6, pp. 641-644.
	GC	Leon Goldman MD., et al., "Biomedical Aspects of Lasers" JAMA, April 20, 1964, Vol. 188, No. 3, pp. 302-306.
	GD	Leon Goldman MD., et al., "Effect of the Laser Beam on the Skin," Preliminary Report, 2 pgs.
	GE	Leon Goldman MD., et al., "Effect of the Laser Beam on the Skin," III. Exposure of Cytological Preparations, pp. 247-251.
	GF	"Pathology of the Effect of the Laser Beam on the Skin," Nature, March 2, 1963, Vol. 197, pp. 912-914.
	GG	"Preliminary Investigation of Fat Embolization from Pulsed Ruby Laser Impacts of Bone," Nature, Vol. 221, Jan. 1969, pp. 361-363.
	GH	Leon Goldman MD., et al., "Radiation from a Q-Switched Ruby Laser: Effect of Repeated Impacts of Power Output of 10 Megawatts on a Tattoo of Man," pp. 69-71.
	GI	
	GJ	
	GK	
	GL	
	GM	
	GN	
	GO	
	GP	

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

February 15, 2005

PATENT
Attorney Docket No.: SCI-00100

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Group Art Unit: 3739
James L. Hobart et al.	Examiner: Shay, D.
Serial No.: 09/018,104	
Filed: February 3, 1998	**AMENDMENT AND RESPONSE TO OFFICE ACTION MAILED ON APRIL 7, 2005**
For: **DUAL MODE LASER DELIVERY SYSTEM PROVIDING CONTROLLABLE DEPTH OF TISSUE ABLATION AND CORRESPONDING CONTROLLABLE DEPTH OF COAGULATION**	162 North Wolfe Road Sunnyvale, California 94086 (408) 530-9700
	Customer No.: 28960

Mail Stop: AF
Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENTS

Sir:

In response to the Office Action mailed on April 7, 2005, please amend the above-titled application as follows:

Remarks/Arguments begin on page 2 of this paper.

REMARKS

The Applicants respectfully request further examination and reconsideration in view of the amendments set forth above and the arguments set forth below. Claims 1-14, 17-24 and 41-51 were pending in this application. Applicants have previously filed a response on July 14, 2004 to a Final Office Action mailed May 14, 2004 amending Claims 1, 11, 17 and 41 and adding new Claims 50 and 51. Because the Applicants did not receive an Advisory Action within six months of the Office Action mailed on May 14, 2004, on November 12, 2004 the Applicants filed a Request for Continued Examination (RCE). Accordingly Claims 1-14, 17-24 and 41-51 are still pending in this Application.

In response to the Applicants' correspondence filed on July 14, 2004 and the RCE filed November 12, 2004, an Office Action was sent on April 7, 2005 rejecting Claims 1-14, 17-24 and 41-51. The rejection of Claims 1-14, 17-24 and 41-51 was made final even though this was the first Office Action after filing the RCE and Claims 1, 11, 17 and 41 had been amended and new Claims 50 and 51 had been added.

Within the Office Action mailed April 7, 2005 it is stated that the rejection of the Claims 1-14, 17-24 and 41-51 has been made final even though it is the first action after filing the RCE and the submission under 37 C.F.R. § 1.114, because all the claims are drawn to the same invention claimed in the application prior to entry or submission under 37 C.F.R. § 1.114 and could have been finally rejected on the grounds and art of record in the next Office Action if they had been entered in the application prior to the entry under 37 C.F.R. § 1.114. An Advisory Action in response to Applicants' correspondence sent July 14, 2004 was eventually mailed on April 13, 2005, almost nine (9) months after the filing of the Applicants' response. Applicants respectfully submit that the finality of the rejection of Claims 1-14, 17-24 and 41-51 in the Office Action mailed on April 7, 2005 is improper.

In response to the previous Office Action mailed May 14, 2004, Applicant amended the claims to recite limitations and combinations of limitations which were not addressed in any previous Office Action and which Applicants contend could not be properly rejected on the art made of record. Accordingly, the Applicants respectfully request the finality of the Office Action be withdrawn.

The Applicants have detailed the differences between the prior art made of record and the claimed invention in a number of previous communications. It is the Applicants' position that the rejection of the Claims 1-14, 17-24 and 41-51 is predicated on an overly broad interpretation of the teaching in the U.S. Patent No. 5,125,922 to Dwyer (hereafter "Dwyer") and/or

combinations of large numbers of references. The medical laser system of Dwyer does not have the structural features of the claimed invention and is not functionally the same as the claimed invention.

Again, Dwyer teaches an apparatus with two lasers producing two different wavelengths. An operator can choose which wavelength is selected by turning on the appropriate laser and shutting off the appropriate laser. However, it not feasible to alternate between pulses or sets of pulses, with an apparatus such as taught by Dwyer, in the time frame required to perform a coagulation or ablation operation on a target area tissue as recited in the claims of the present invention. Within the present Office Action, these arguments are cursorily disregarded because it is stated that Dwyer teaches a medical laser that can ablate and coagulate tissue and the switching between the two functions can be done quickly.

While, the present invention is directed to a medical laser that has a plurality of laser sources and which can change between ablation and coagulation mode, these are not the only features that are being claimed. Specifically, the present invention is also directed to a medical laser that uses laser pulses from each of the plurality of laser sources and combines the pulses to form a laser output of the combined pulses while the medical laser is in at least one of ablation mode or coagulation mode. In order to accomplish this goal, a galvanometer is preferably used to rapidly switch between the pulses from each of the laser sources. Applicants contend that the medical laser system of Dwyer can not operate to switch between laser sources on a pulse time scale, such that the pulses from both lasers can be combined while operating in at least one of the ablation mode and coagulation mode. Claims 50 and 51 have been added to specifically recite a galvanometer as well as the other features described above.

By way of the previous amendments, the Applicants have amended the independent Claim1 to recite a medical laser delivery apparatus for delivering a series of laser pulses having a wavelength, in order to clearly state that the series of laser pulses have laser light at the wavelength. Within the present Office Action it is stated that "comprising-type" claim language allows more than one wavelength to exist in the laser output. It is further stated that the originally filed disclosure does not provide support for both lasers to produce pulses of the same wavelength. While the laser light can include more than one wavelength, Applicants contend that does not preclude or render irrelevant the limitation of laser pulses from more than one laser source having the wavelength, (viz. the same wavelength). Further, it is a fact of physics that lasers of the "same kind" by definition produce laser light of the same wavelength. Laser light is a property of the lasing material and lasers made from the same material, will lase with the same

wavelength or wavelengths. Accordingly, in the absence of any modifying optics and/or filters, pulses from two or more lasers of the same kind will have laser light at the same wavelength and can, therefore, be combined to produce a laser output having the wavelength.

In summary, Dwyer is a medical laser system with lasers that operate at two different wavelengths. In use, an operator can switch between lasers to produce two corresponding laser outputs, one with a first wavelength for ablation and one with a second wavelength for coagulation. However, Dwyer does not teach or suggest combining pulses from the same kind of laser, the pulses having a wavelength and wherein the combined pulses produce a laser output at the wavelength while operating in at least one of ablation mode or coagulation mode. Applicant contends that these as well as a number of other distinguishing features are clearly recited in each of the independent Claims 1, 11, 17, 41, 50 and 51.

Rejections Under 35 U.S.C. § 102

Within the Office Action, Claims 1, 11, and 41 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Dwyer. Applicants respectfully disagree and contend that each of the Claims 1, 11, and 41 clearly recite features not taught or suggested by Dwyer, such as those described in detail above and below.

Specifically, the independent Claim 1 is directed to a medical laser delivery apparatus for delivering a series of laser pulses having *a wavelength*, the medical laser delivery apparatus including non-ablative laser pulses for directing to an area of tissue to be treated and generating a region of coagulation to a controllable coagulation depth under a surface of the area of tissue. The apparatus comprises a laser source for generating the series of laser pulses including the non-ablative laser pulses to be delivered to the area of tissue to be treated in order to raise a temperature at the surface of the area of tissue to be treated to a temperature sufficient to generate coagulation at the coagulation depth when the laser source is in a coagulation mode. The laser source comprises two or more lasers that combine the series of laser pulses from the two or more lasers. As discussed above, Dwyer fails to teach a medical laser delivery apparatus which has a laser source with two or more lasers having *a wavelength* that are combined to form a single output to generate conditions for ablation and coagulation. For at least these reasons, the independent Claim 1 is allowable over the teachings of Dwyer.

The independent Claim 11 is directed to a medical laser comprising a laser source having two or more pulsed lasers for generating pulses of laser light having *a wavelength*, wherein a series of the pulses of laser light are combined from the laser source for generating a single laser

output having a predetermined absorption, wherein the predetermined absorption forms a predetermined coagulation depth and a laser control system coupled to the laser source for controlling the laser source to deliver the laser output to a target area. As discussed above, Dwyer fails to teach a medical laser delivery apparatus which has a laser source with two or more lasers having *a wavelength* that are combined to form a single output to generate conditions for ablation and coagulation. For at least these reasons, the independent Claim 11 is allowable over the teachings of Dwyer.

The independent Claim 41 is directed to a dual mode medical laser system, for sequentially ablating and coagulating a region of target tissue with ablation laser pulses followed by coagulation laser pulses. The dual mode medical laser system comprises a laser source comprising a first laser and a second laser for generating a first set of laser pulses and a second set of laser pulses at *a wavelength*, means to combine pulses of the first set of laser pulses and the second set of laser pulses to provide a single laser output, the single laser output being capable of coagulating tissue with the system in a coagulation mode and ablating tissue with the system in an ablating mode and means to direct the single laser output to the region of the target tissue. As discussed above, Dwyer fails to teach a system capable of coagulating tissue with the system in a coagulation mode, and ablating tissue with the system in ablation mode which combines laser pulses having *a wavelength* from multiple lasers to generate a single laser output. For at least these reasons, the independent Claim 41 is allowable over the teachings of Dwyer.

Rejections Under 35 U.S.C. § 103

Within the Office Action, Claims 1-3, 8, 41, 43, 44 and 47-51 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,672,969 to Dew (hereinafter "Dew") in combination with, U.S. Patent No. 5,620,435 to Belkin et al. (hereinafter "Belkin et al.") and, the article entitled "Selective Photothermolysis: Precise Microsurgery by Selective Absorption of Pulsed Radiation" by R. Rox Anderson and John A. Parrish (hereinafter "Anderson et al."). The Applicants respectfully traverse the rejection of Claims 1-3, 8, 41, 43, 44 and 47-51 under 35 U.S.C. § 103(a) as being unpatentable over Dew in combination with Belkin et al. and Anderson et al. for the following reasons.

Dew teaches a laser healing method to effect wound closure and reconstruction of biological tissue. Optical energy is applied to produce thermal heating of biological tissue to a degree suitable for denaturing the tissue proteins such that the collagenous elements of the tissue form a biological glue to seal and reconstruct the tissue being heated. [Dew, Abstract] The

system of Dew includes a laser 20. Dew teaches a marker laser 30 which is co-aligned with the infrared beam of the laser 20. Further, Dew teaches that an auxiliary source of optical energy 50 can be incorporated into the apparatus to emit radiation having a wavelength which is intensely absorbed by biological tissue. Dew does not teach a medical laser with a laser source having two or more lasers having a wavelength, wherein pluses from the two or more lasers combined for generating a laser output at the wavelength while operating in at least one of the ablation mode and coagulation mode.

Belkin et al. teaches a method for welding ocular tissues to each other using a carbon dioxide laser. [Belkin et al., col. 2, lines 35-44] Belkin et al. do not teach a medical laser with a laser source with two or more lasers. Belkin et al. do not teach a medical laser with a laser source having two or more lasers having a wavelength, wherein pluses from the two or more lasers combined for generating a laser output at the wavelength while operating in at least one of the ablation mode and coagulation mode.

Anderson et al. teach a scheme for confining thermally mediated radiation damage to chosen pigmented targets. [Anderson et al., p. 524] The technique relies on selective absorption of a brief radiation pulse to generate and confine heat at certain pigmented targets. [Anderson et al., p. 524] Anderson et al. do not teach a medical laser with a laser source having two or more lasers having a wavelength, wherein pluses from the two or more lasers combined for generating a laser output at the wavelength while operating in at least one of the ablation mode and coagulation mode.

Neither Dew, Belkin, Anderson et al., nor their combination teach or suggest a medical laser with a laser source having two or more lasers having a wavelength, wherein pluses from the two or more lasers combined for generating a laser output at the wavelength while operating in at least one of the ablation mode and coagulation mode or means for combining pulses from two or more lasers. These features as well as other distinguishing features are recited in the independent Claims 1, 41, 50 and 51. For at least these reasons, the independent Claims 1, 41, 50 and 51 are allowable over the teachings of Dew, Belkin et al., Anderson et al. and their combination.

Specifically, the independent Claim 1 recites a medical laser delivery apparatus for delivering a series of laser pulses having *a wavelength*, the medical laser delivery apparatus including non-ablative laser pulses for directing to an area of tissue to be treated and generating a region of coagulation to a controllable coagulation depth under a surface of the area of tissue, the apparatus comprising a laser source for generating the series of laser pulses including the non-ablative laser pulses to be delivered to the area of tissue to be treated in order to raise a

temperature at the surface of the area of tissue to be treated to a temperature sufficient to generate coagulation at the coagulation depth when the laser source is in a coagulation mode, wherein the laser source comprises two or more lasers that combines the series of laser pulses from the two or more lasers. As discussed above, neither Dew, Belkin et al., Anderson et al. nor their combination teach or make obvious a laser delivery apparatus for delivering a series of laser pulses having *a wavelength* comprising a laser source with two or more lasers that combines a series of laser pulses from the two or more lasers. For at least these reasons, the independent Claim 1 is allowable over the teachings of Dew, Belkin, Anderson and their combination.

Claims 2, 3 and 8 are all dependent on the independent Claim 1. As described above, the independent Claim 1 is allowable over the teachings of Dew, Belkin et al., Anderson et al. and their combination. Accordingly, Claims 2, 3 and 8 are all also allowable as being dependent upon an allowable base claim.

The independent Claim 41 is directed to a dual mode medical laser system, for sequentially ablating and coagulating a region of target tissue with ablation laser pulses followed by coagulation laser pulses, the dual mode medical laser system comprising a laser source comprising a first laser and a second laser for generating a first set of laser pulses and a second set of laser pulses at *a wavelength*; means to combine pulses of the first set of laser pulses and the second set of laser pulses to provide a single laser output, the single laser output being capable of coagulating tissue with the system in a coagulation mode and ablating tissue with the system in an ablating mode and means to direct the single laser output to the region of the target tissue. As discussed above, neither Dew, Belkin et al., Anderson et al. nor their combination teach or make obvious a medical laser system for delivering a series of laser pulses having comprising a laser source comprising a first laser and a second laser for generating a first set of laser pulses and a second set of laser pulses at *a wavelength*; means to combine pulses of the first set of laser pulses and the second set of laser pulses to provide a single laser output, the single laser output being capable of coagulating tissue with the system in a coagulation mode and ablating tissue with the system in an ablating mode. For at least these reasons, the independent Claim 41 is allowable over the teachings of Dew, Belkin et al., Anderson et al. and their combination.

Claims 43, 44 and 47-49 are all dependent on the independent Claim 41. As described above, the independent Claim 41 is allowable over the teachings of Dew, Belkin et al., Anderson et al. and their combination. Accordingly, Claims 43, 44 and 47-49 are also all allowable as being dependent upon an allowable base claim.

The independent Claim 50 is directed to a medical laser delivery apparatus for delivering a series of laser pulses having a wavelength, the medical laser delivery apparatus including non-ablative laser pulses for directing to an area of tissue to be treated and generating a region of coagulation to a controllable coagulation depth under a surface of the area of tissue, the apparatus comprising a laser source for generating the series of laser pulses including the non-ablative laser pulses to be delivered to the area of tissue to be treated in order to raise a temperature at the surface of the area of tissue to be treated to a temperature sufficient to generate coagulation at the coagulation depth when the laser source is in a coagulation mode, wherein the laser source comprises two or more lasers, the medical laser delivery apparatus further comprising a galvanometer that combines the series of laser pulses from the two or more lasers into a single laser output by switching between laser outputs from the two or more lasers. As discussed above, neither Dew, Belkin et al., Anderson et al. nor their combination teach or make obvious a medical laser delivery apparatus for delivering a series of laser pulses having a wavelength from a laser source comprises two or more lasers, and a galvanometer that combines the series of laser pulses from the two or more lasers into a single laser output by switching between laser outputs from the two or more lasers. For at least these reasons, the independent Claim 50 is allowable over the teachings of Dew, Belkin et al., Anderson et al. and their combination.

The independent Claim 51 is directed to a medical laser delivery apparatus for delivering a series of laser pulses having a wavelength, the medical laser delivery apparatus including non-ablative laser pulses for directing to an area of tissue to be treated and generating a region of coagulation to a controllable coagulation depth under a surface of the area of tissue, the apparatus comprising a laser source for generating the series of laser pulses including the non-ablative laser pulses to be delivered to the area of tissue to be treated in order to raise a temperature at the surface of the area of tissue to be treated to a temperature sufficient to generate coagulation at the coagulation depth when the laser source is in a coagulation mode, wherein the laser source comprises two or more lasers, the medical laser delivery apparatus further comprising a galvanometer that combines the series of laser pulses from the two or more lasers into a single laser output by switching between laser outputs from the two or more lasers. As discussed above, neither Dew, Belkin et al., Anderson et al. nor their combination teach or make obvious a laser delivery apparatus with a laser source comprises two or more lasers and a galvanometer that combines the series of laser pulses from the two or more lasers into a single laser output by

switching between laser outputs from the two or more lasers. For at least these reasons, the independent Claim 51 is allowable over the teachings of Dew, Belkin et al., Anderson et al. and their combination.

Within the Office Action, Claims 1, 6, 7, 11-13, 17, 18, 41 and 44-46 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,098,426 to Sklar et al. (hereinafter "Sklar et al.") in combination with Dwyer. The Applicants respectfully traverse the rejection of Claims 1, 6, 7, 11-13, 17, 18, 41 and 44-46 under 35 U.S.C. § 103(a) as being unpatentable over Sklar et al. in combination with Dwyer for the following reasons.

Sklar et al. teach a system and method for accurately controlling and positioning laser sources, specifically during surgery. According to Sklar et al. "a limiting factor to the duration of the operation under these procedures (viz. Prior Art procedures) is the surgeon's reaction time while focusing on the target and the patients movement while the surgeon is trying to find the target and react to the target recognition by firing the laser. [Sklar et al., column 5, lines 13-19] In view of these prior art limitations, Sklar et al. teach a system for performing precision laser surgery which includes an imaging system for providing a surgeon with precision tracking and topographical information regarding the surgical target area. [Sklar et al., Abstract] Sklar et al. state that "it is well appreciated that the limitations on the achievable accuracy and control of laser surgical instruments today is no longer paced by the development of laser technology, but by the imaging and tracking technologies needed to efficiently use the laser." [Sklar et al., column 2, lines 39-43]

In other words the teachings of Sklar et al. are directed to laser tracking and not a laser delivery system in accordance with the teachings of the present Application. Even if the teachings of Sklar et al. in combination with the teachings of Dew, Belkin et al. and Anderson et al. were appropriate, Sklar et al. do not teach a medical laser with a laser source having two or more lasers having a wavelength, wherein pluses from the two or more lasers combined for generating a laser output at the wavelength while operating in at least one of the ablation mode and coagulation mode.

Further it is noted that from the description that the tracking system of Sklar et al. can be used with any number of laser sources. Sklar et al. state that "the therapeutic laser may be a frequency multiplied solid state laser which may be either flash lamp or diode pumped, or an argon, argon pumped dye, excimer, excimer pumped dye, nitrogen, nitrogen pumped dye, or any host of different lasers or combinations thereof." [Sklar et al., column 16, lines 60-68] The mere recitation of a "combination" of lasers does not suggest or teach the particular configuration of

lasers claimed in the instant application. The recitation of a "combination" of lasers is interpretable to mean independently operable lasers, combination laser and pumping lasers and any other imaginable "combination."

Dwyer is characterized above. Neither Sklar et al., Dwyer nor their combination teaches or suggests combining laser pulses from a laser source comprising two or more lasers having a wavelength to generate a single laser output for coagulating or ablating tissue. These features, as well as other distinguishing features, are recited in the independent Claims 1, 11, 17 and 41. For at least these reasons, the independent Claims 1, 11, 17 and 41 are allowable over the teachings of Sklar et al., Dwyer and their combination.

Specifically, the independent Claim 1 recites a medical laser delivery apparatus for delivering a series of laser pulses having *a wavelength*, the medical laser delivery apparatus including non-ablative laser pulses for directing to an area of tissue to be treated and generating a region of coagulation to a controllable coagulation depth under a surface of the area of tissue, the apparatus comprising a laser source for generating the series of laser pulses including the non-ablative laser pulses to be delivered to the area of tissue to be treated in order to raise a temperature at the surface of the area of tissue to be treated to a temperature sufficient to generate coagulation at the coagulation depth when the laser source is in a coagulation mode, wherein the laser source comprises two or more lasers that combines the series of laser pulses from the two or more lasers. As discussed above, neither Sklar et al., Dwyer nor their combination teach or make obvious a laser delivery apparatus for delivering a series of laser pulses having *a wavelength* comprising a laser source with two or more lasers that combines a series of laser pulses from the two or more lasers. For at least these reasons, the independent Claim 1 is allowable over the teachings of Sklar et al., Dwyer and their combination.

Claims 6 and 7 are both dependent on the independent Claim 1. As described above, the independent Claim 1 is allowable over the teachings of Sklar et al., Dwyer and their combination. Accordingly, Claims 6 and 7 are both also allowable as being dependent upon an allowable base claim.

The independent Claims 11 is directed to a medical laser comprising a laser source having two or more pulsed lasers for generating pulses of laser light having *a wavelength*, wherein a series of the pulses of laser light are combined from the laser source for generating a single laser output having a predetermined absorption, wherein the predetermined absorption forms a predetermined coagulation depth and a laser control system coupled to the laser source for controlling the laser source to deliver the laser output to a target area. As discussed above,

neither Sklar et al., Dwyer nor their combination teach or make obvious a medical laser comprising a laser source having two or more pulsed lasers for generating pulses of laser light having *a wavelength.* For at least these reasons, the independent Claim 11 is allowable over the teachings of Sklar et al., Dwyer and their combination.

Claims 12 and 13 are both dependent on the independent Claim 11. As described above, the independent Claim 11 is allowable over the teachings of Sklar et al., Dwyer and their combination. Accordingly, Claims 12 and 13 are also both allowable as being dependent upon an allowable base claim.

The independent Claim 17 is directed to a medical laser delivery apparatus for treating an area of tissue comprising a laser source having a first laser and a second laser each of which generate laser pulses having *a wavelength*, the laser source being configured to combine laser pulses of the first laser and the second laser to form a single laser output by a combining apparatus for delivering a series of laser pulses each having a strength and a duration to ablate or coagulate the area of tissue being treated a laser delivery system coupled to the laser source for delivering the laser pulses from the laser source to the area of tissue being treated and a control system for selecting the rate and fluence of the laser pulses, the control system coupled to the laser source for controlling generation of the laser pulses from the laser source, wherein the laser source operates in both an ablation mode and a coagulation mode such that when in the ablation mode, the strength and duration of the laser pulses are sufficient to ablate tissue at the area of tissue being treated to a controllable ablation depth and when in the coagulation mode, the strength and duration of the laser pulses are sufficient to generate a coagulation region having a controllable coagulation depth within the tissue remaining at the area of tissue being treated without ablating any tissue. As discussed above, neither Sklar et al., Dwyer nor their combination teach or make obvious medical laser delivery apparatus for treating an area of tissue comprising a laser source having a first laser and a second laser each of which generate laser pulses having *a wavelength*, the laser source being configured to combine laser pulses of the first laser and the second laser to form a single laser output. For at least these reasons, the independent Claim 17 is allowable over the teachings of Sklar et al., Dwyer and their combination.

Claim 18 is dependent on the independent Claim 17. As described above, the independent Claim 17 is allowable over the teachings of Sklar et al., Dwyer and their combination. Accordingly, Claim 18 is also allowable as being dependent upon an allowable base claim.

The independent Claim 41 is directed to a dual mode medical laser system, for sequentially ablating and coagulating a region of target tissue with ablation laser pulses followed by coagulation laser pulses, the dual mode medical laser system comprising a laser source comprising a first laser and a second laser for generating a first set of laser pulses and a second set of laser pulses at *a wavelength*; means to combine pulses of the first set of laser pulses and the second set of laser pulses to provide a single laser output, the single laser output being capable of coagulating tissue with the system in a coagulation mode and ablating tissue with the system in an ablating mode and means to direct the single laser output to the region of the target tissue. As discussed above, neither Sklar et al., Dwyer nor their combination teach or make obvious a medical laser system for delivering a series of laser pulses having comprising a laser source comprising a first laser and a second laser for generating a first set of laser pulses and a second set of laser pulses at *a wavelength*; means to combine pulses of the first set of laser pulses and the second set of laser pulses to provide a single laser output, the single laser output being capable of coagulating tissue with the system in a coagulation mode and ablating tissue with the system in an ablating mode. For at least these reasons, the independent Claim 41 is allowable over the teachings of Dew, Belkin, Anderson and their combination.

Claims 44-46 are all dependent on the independent Claim 41. As described above, the independent Claim 41 is allowable over the teachings of Sklar et al., Dwyer and their combination. Accordingly, Claims 44-46 are also all allowable as being dependent upon an allowable base claim.

Within the Office Action, Claims 4, 9, 10, 42 and 52 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Dew in combination with Anderson et al., Belkin et al. and further in view of U.S. Patent No. 5,938,657 to Assa et al. (hereafter "Assa et al.").

Assa et al. teach an apparatus for delivering energy with a continuous output and can not be combined with Dew, Anderson et al. or Belkin et al., either singularly or in combination, teach the combination of features taught and claimed in the instant application. Again, the inordinate number of combined references is inconsistent with establishing a prima facie case of obviousness and there is no hint, teaching or suggestion in the prior art to combine the references in a way which would produce the invention as claimed in the instant application. Neither Dew, Anderson et al., Belkin et al., Assa et al. nor their combination teaches or suggests combining laser pulses from a laser source comprising two or more lasers having a wavelength to generate a single laser output while in at least one of coagulating or ablating mode.

Claims 4, 9, 10 and 52 are all dependent on the independent Claim 1, and Claim 42 is dependent on the independent Claim 41. As described above, the independent Claims 1 and 41 are both allowable over the teachings Dew, Belkin et al., Anderson et al. and their combination. Accordingly, Claims 4, 9, 10, 41 and 52 are also all allowable as being dependent upon allowable base claims.

Within the Office Action, Claims 14 and 19-22 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Dew in combination with Anderson et al. and Belkin et al. and further in view of Sklar et al.

As previously described neither Dew, Anderson et al., Belkin et al., Sklar et al. nor their combination teach or suggest a medical laser comprising a laser source having two or more pulsed lasers for generating pulses of laser light having *a wavelength,* such as recited in the independent Claim 11. For at least these reasons, the independent Claim 11 is allowable over the teachings of Dew, Anderson et al., Belkin et al., Sklar et al. and their combination.

Claims 14 and 19-22 are all dependent on the independent Claim 11. As described above the independent Claim 11 is allowable over the teaching of Sklar et al., Dwyer and their combination. Accordingly, Claims 14 and 19-22 are also all allowable as being dependent on an allowable base claim.

Within the Office Action, Claims 23 and 24 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Dew in combination with Anderson et al., Belkin et al., Sklar and further in view of Assa et al.

Again, neither Dew, Anderson et al., Belkin et al., Sklar, Assa et al., nor their combination teach or suggest a medical laser delivery apparatus for treating an area of tissue comprising a laser source having a first laser and a second laser each of which generate laser pulses having *a wavelength*, the laser source being configured to combine laser pulses of the first laser and the second laser to form a single laser output, such as recited in the independent Claim 17. For at least these reasons, the independent Claim 17 is allowable over the teachings of Dew, Anderson et al., Belkin et al., Sklar, Assa et al. and their combination.

Claims 23 and 24 are both dependent on the independent Claim 17. As described above, the independent Claim 17 is allowable over the teachings of Sklar, Dwyer and their combination. Accordingly, Claims 23 and 24 are both also allowable as being dependent upon an allowable base claim.

For the all of the reasons given above, Applicants respectfully submit that the claims are in a condition for allowance, and allowance at an early date would be appreciated. Should the Examiner have any questions or comments, he is encouraged to call the undersigned at (408) 530-9700 to discuss them so that any outstanding issues can be expeditiously resolved.

Respectfully submitted,
HAVERSTOCK & OWENS LLP

Dated: June 7, 2005 By: Jonathan O. Owens

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/018,104	02/03/1998	JAMES L. HOBART	PHAN-00100	9278

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EXAMINER	
SHAY, DAVID M	

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3739	

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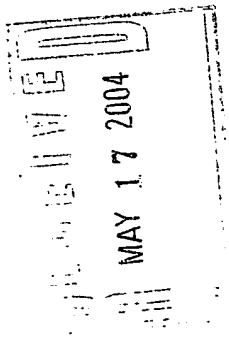
Please find below and/or attached an Office communication concerning this application or proceeding.



Office Action Summary

Application No.	Applicant(s)
09/618,104	Hobart
Examiner	**Group Art Unit**
D. Shay	3739

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on December 1, 2003.

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1-4,6-14,17-24, & 41-49 is/are pending in the application.

Of the above claim(s)_____ is/are withdrawn from consideration.

☐ Claim(s)_____ is/are allowed.

☒ Claim(s) 1-4,6-14,17-24, & 41-49 is/are rejected.

☐ Claim(s)_____ is/are objected to.

☐ Claim(s)_____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on_____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on_____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number)_____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received:_____.

Attachment(s)

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 38, 41, 42a

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other_____

Office Action Summary

The rejections under 35 U.S.C. 112, first paragraph, set forth in the previous office actions are hereby withdrawn in view of applicants amendments.

Regarding the rejection under 35 U.S.C. 102 set forth in the previous office action, applicant argues that Dwyer et al fail "to teach a laser source having multiple lasers, wherein pulses of the laser source are combined to generate a single laser output or a single operative condition such as coagulation or ablation when the system is in coagulation mode or ablation mode, respectively." The remarks by applicant are noted, however these are not convincing. As already noted in a previous office action with regard to the teachings of Dwyer and the applicability thereof to claims 17 and 41, applicant's attention is respectfully invited to Figure 3 of Dwyer et al and the attendant disclosure. Figure 3 shows two lasers (35 and 36) which are controlled by a wavelength selecting switch (38) and whose outputs are combined at beam splitter (37). This is stated at column 4, lines 12-22 of Dwyer et al. It is noted that the pulses produced by the lasers of Dwyer et al must have both a power and duration else they would not exist.

These are the structures required by claim 17. The claim does contain a functional statement regarding the function of the control system: "for controlling generation of the laser pulses..." The examiner first notes that this recitation is not of the proper form to invoke 35 USC 112; sixth paragraph (see MPEP 2181) thus the function is accorded little weight. Secondly, the functional recitation merely recites that the coagulation depth be controllable and since Dwyer et al teach that the "respective lasers are turned on and off as desired" (see column

4, lines 20 and 21) this is considered to provide the recited controllability, even assuming that the claim language in question were crafted to invoke the sixth paragraph of 35 U.S.C. 112.

Regarding claim 41, applicant's attention is once again invited to Figure 3 of Dwyer et al and lines 12-22 in column 4 thereof and the structures set forth above. Additionally optical fiber 21 constitutes a " means to direct." as recited in the claim. It is noted that the ability of the switch to provide pulses from alternating lasers renders it a " means to alternate between pulses of the first set of laser pulses and pulses of the second set of laser pulses " as claimed.

As set forth above, the pulses of the two lasers in Figure 3 of Dwyer et al are combined at beam splitter (37) and steered to a single output path, the optical fiber (21), from which the pulses of both lasers exist to treat the tissue. The combined pulses, generated by the source of Dwyer et al enable either coagulation or cutting at the desire of the surgeon. The examiner once again notes that applicant has chosen to make arguments without pointing to specific structure which is lacking in Dwyer et al that prevents the reference from reading on the claims. As set forth previously, such arguments are not persuasive in view of the specific structures laid out by the examiner which provide the functions which applicant alleges are absent from Dwyer et al.

With regard to the rejection under 35 U.S.C. 103, applicant makes reference to a previous characterization wherein applicant argues each reference singly with no regard to what the combined teachings would suggest to one having ordinary skill in the art. Applicant also argues, without any rationale other than the aforementioned piecemeal treatment of the applied

references that a prima facie case of obviousness has not been made. These characterizations are not convincing for the reasons set forth previously. As set forth above Dwyer et al teach beam combining and controllable coagulation. Since this the apparent basis upon which applicant argues the patentability of all the claims, all of applicants arguments are not convincing. It is noted that claim 5 does not appear in the amendment, as applicant has requested replacement of all prior versions of the claims, claim 5 will be treated as cancelled.

Claims 1, 11, 17 and 41 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Dwyer et al.

Claims 1-3, 8, 41, 43, 44, and 47-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dew ('969) in combination with Anderson et al, and Belkin et al. Dew ('969) teaches the use of a carbon dioxide laser operating at 10.6 microns as a cutting laser in a laser system comprised of multiple lasers and teaches that the power of a pulse determines the amount of heat deposited in the tissue and that the same type of laser can be used for cutting and coagulating. Belkin et al teach that the carbon dioxide lasers operating at 10.6 microns can be used to heat rather than cut tissue. Anderson et al teach the way parameters such as absorptivity, spot size, and pulse width interrelate to control the amount of energy absorbed by tissue. It would have been obvious to the artisan of ordinary skill to use a carbon dioxide laser to coagulate in the device of Dew ('969), since this laser can be configured to coagulate as taught by Belkin et al, and since this would render the device more versatile, at no extra cost; and to employ the particular laser parameters claimed since these provide no unexpected result, and are

within the scope of one having ordinary skill in the art as shown by Anderson et al; to employ an articulated arm with refocusing convex lenses since these are notorious in the art for transporting infrared radiation such as that from Carbon dioxide lasers, official notice of which has already taken; and to use a galvanometer to alternate the beams, since these are notorious for moving optical components official notice which has already been taken thus producing a device such as claimed.

Claims 1, 6, 7, 11-13, 17, 18, 41 and 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sklar et al in combination with Dwyer et al. Sklar et al teach the use of a graphic user interface for use with multiple lasers and teach that it can be used with any type of laser for any type of surgery and that the depth of laser action can be input and displayed. Dwyer et al provide the teachings set forth above. It would have been obvious to the artisan of ordinary skill to employ the interface of Sklar et al in the device of Dwyer et al, since Dwyer et al provide no control interface for the device made up of two separate lasers or to employ the laser source of Dwyer et al in the system of Sklar et al, since Sklar et al provide no particular laser source, thus producing a device such as claimed.

Claims 4, 9, 10, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dew ('969) in combination with Anderson et al and Belkin et al as applied to claims 1-3, 8, 41, 43, 44, and 47-49 are above, and further in combination with Assa et al. Assa et al teach a scanning handpiece and the equivalence of carbon dioxide and Erbium YAG lasers. Thus it would have been obvious to the artisan or ordinary skill to employ and handpiece as taught by

Assa et al, since this allows more consistency of treatment and to employ an erbium laser, since these are equivalent to the carbon dioxide laser, thus producing a device such as claimed.

Claims 14 and 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dew ('969) in combination with Anderson et al and Belkin et al as applied to claims 1-3, 8, 41, 43, 44 and 47-49 above, and further in combination with Sklar et al. Sklar et al teach a user interface for a multi-laser system. It would have been obvious to the artisan of ordinary skill to employ the interface of Sklar et al, since no interface is taught and this would allow the surgical treatment to be preprogrammed, as taught by Sklar et al, thus producing a device such as claimed.

Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dew ('969) in combination with Anderson et al, Belkin et al, and Sklar et al as applied to claims 14 and 19-22 above, and further in combination with Assa et al. The teachings of Assa et al and the motivations for combination thereof are essentially those already iterated above. Thus it would have been obvious to the artisan of ordinary skill to combine these old and well known teachings to produce a device such as claimed.

Applicant's arguments filed December 1, 2003 have been fully considered but they are not persuasive as set forth above.

This is a Request for Continued Examination of applicant's earlier Application No. 09/018,104. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to David Shay at telephone number 308-2215.

Shay/Dl

April 19, 2004

DAVID M. SHAY
PRIMARY EXAMINER
GROUP 330

FORM PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No.: SCI-00100	Serial No.: 09/018,104
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use Several Sheets If Necessary)		Applicants: James L. Hobart et al.	
(37 CFR § 1.98(b))		Filing Date: February 3, 1998	Group Art Unit: 3739

U.S. PATENT DOCUMENTS

Examiner Initials		Serial / Patent Number	Issue Date	Applicant / Patentee	Class	Subclass	Filing Date
	AA	6,471,691 B1	10/29/02	Kobayashi et al.	606	4	08/19/99
	AB	6,524,330 B1	02/25/03	Khoobehi et al.	~~607~~	89	10/27/00
	AC	US 2003/0032949 A1	02/13/03	Schuele et al.	~~606~~	4	07/24/02
	AD	US 2003/0078567 A1	04/24/03	Dorin et al.	~~606~~	4	09/27/02
	AE						
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	AL						
	AM						
	AN						
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FOREIGN PATENTS OR PUBLISHED FOREIGN PATENT APPLICATIONS

		Document Number	Publication Date	Country / Patent Office	Class	Subclass	Translation	
							Yes	No
	AP							
	AQ							
	AR							
	AS							
	AT							

OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)

	AU	
	AV	
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	BA	
	BB	
	BC	

Examiner: [signature] Date Considered: April 15, 2004

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No.: SCI-00100	Serial No.:09/018,104
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use Several Sheets If Necessary)		Applicant: James L. Hobart et al.	
(37 CFR § 1.98(b))		Filing Date: February 3, 1998	Group Art Unit: 3739

U.S. PATENT DOCUMENTS

Examiner Initials		Serial / Patent Number	Issue Date	Applicant / Patentee	Class	Subclass	Filing Date
	AA	6,270,222 B1	08/07/01	Herpst	359	511	04/09/99
	AB	5,781,574	07/14/98	Conners et al.	372	35	06/12/97
	AC	US2001/0029364 A1	10/11/01	Almeida	606	9	04/25/01
	AD	US2001/0007068 A1	07/05/01	Ota et al.	606	9	02/01/01
	AE						
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FOREIGN PATENTS OR PUBLISHED FOREIGN PATENT APPLICATIONS

		Document Number	Publication Date	Country / Patent Office	Class	Subclass	Translation	
							Yes	No
	AP	EP 1 057 454 A2	12/06/00	Europe	A61B	18/20	X	
	AQ							
	AR							
	AS							
	AT							

OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)

	AU	
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Examiner: [signature] Date Considered: April 16, 2004

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 (Modified) — U.S. Department of Commerce, Patent and Trademark Office

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several Sheets If Necessary)

(37 CFR § 1.98(b))

Attorney Docket No.: SCI-00100	Serial No.: 09/018,104
Applicant: James L. Hobart	
Filing Date: 02/03/98	Group Art Unit: 3739

U.S. PATENT DOCUMENTS

Examiner Initials		Serial / Patent Number	Issue Date	Applicant / Patentee	Class	Subclass	Filing Date
	AA	6,613,042 B1	09/02/03	Tankovich et al.	~~606~~	~~10~~	06/30/00
	AB	5,984,915	11/16/99	Loeb et al.	606	~~9~~	10/08/97
	AC	5,738,677	04/14/98	Colvard et al.	~~606~~	~~4~~	05/31/95
	AD	5,522,813	06/04/96	Trelles	~~606~~	~~2~~	09/23/94
	AE	4,601,037	07/15/86	McDonald	~~372~~	~~25~~	06/13/84
	AF	4,391,275	07/05/83	Fankhauser et al.	~~128~~	~~303.1~~	11/28/80
	AG	4,309,998	01/12/82	Aron nee Rosa et al.	~~128~~	~~303.1~~	06/08/79
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	AM						
	AN						
	AO						

FOREIGN PATENTS OR PUBLISHED FOREIGN PATENT APPLICATIONS

	Document Number	Publication Date	Country / Patent Office	Class	Subclass	Translation Yes	Translation No
~~AP~~							
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AS							
~~AT~~							

OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)

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Examiner: [signature] Date Considered: April 15, 2004

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

PATENT
Attorney Docket No.: SCI-00100

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Group Art Unit: 3739
James L. Hobart et al.	Examiner: Shay, D.
Serial No.: 09/018,104	
Filed: February 3, 1998	**AMENDMENT AND RESPONSE TO OFFICE ACTION MAILED ON MAY 14, 2004**
For: **DUAL MODE LASER DELIVERY SYSTEM PROVIDING CONTROLLABLE DEPTH OF TISSUE ABLATION AND CORRESPONDING CONTROLLABLE DEPTH OF COAGULATION**	162 North Wolfe Road Sunnyvale, California 94086 (408) 530-9700
	Customer No.: 28960

MS: Non-Fee Amendment
Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENTS

Sir:

In response to the Office Action mailed on May 15, 2004, please amend the above-titled application as follows:

Amendments to the Claims are reflected in the listing of claims, which begins on page 2 of this paper.

Remarks/Arguments begin on page 8 of this paper.

Amendments to the claims:

This listing of claims will replace all prior versions and listings of Claims in the Application:

Listing of Claims:

1. (Currently Amended) A medical laser delivery apparatus for delivering a series of laser pulses having a wavelength, the medical laser delivery apparatus including non-ablative laser pulses for directing to an area of tissue to be treated and generating a region of coagulation to a controllable coagulation depth under a surface of the area of tissue, the apparatus comprising a laser source for generating the series of laser pulses including the non-ablative laser pulses to be delivered to the area of tissue to be treated in order to raise a temperature at the surface of the area of tissue to be treated to a temperature sufficient to generate coagulation at the coagulation depth when the laser source is in a coagulation mode, wherein the laser source comprises two or more lasers that combines the series of laser pulses from the two or more lasers ~~when the laser source is in an ablation mode~~.

2. (Previously Presented) The medical laser delivery apparatus as claimed in claim 1 wherein the series of laser pulses are focussed to the target tissue through an articulated arm feature.

3. (Previously Presented) The medical laser delivery apparatus as claimed in claim 2 wherein the articulated arm feature comprises one or more refocussing optics for refocussing the laser pulses as they travel through the articulated arm feature.

4. (Previously Presented) The medical laser delivery apparatus as claimed in claim 3 wherein the laser delivery system further comprises a scanning handpiece at an end of the articulated arm feature for guiding the series of one or more non-ablative laser pulses to the area of tissue being treated.

5. (Original) The medical delivery apparatus as claimed in claim 4 wherein the refocussing optics are simple convex lenses.

6. (Original) The medical laser delivery apparatus as claimed in claim 1 further comprising a graphical user interface through which a user selects the coagulation depth and/or fluence.

7. (Original) The medical laser delivery apparatus as claimed in claim 6 wherein the laser source also has an ablation mode wherein it generates laser pulses of a strength and duration to ablate tissue at the area of tissue being treated to an ablation depth and the user selects the ablation depth through the graphical user interface.

8. (Previously Presented) The medical laser delivery apparatus as claimed in claim 1 wherein the apparatus is configured to generate laser pulses with short penetration depths.

9. (Previously Presented) The medical laser delivery apparatus as claimed in claim 8 wherein the two or more lasers are erbium lasers.

10. (Previously Presented) The medical laser delivery apparatus as claimed in claim 9 wherein the erbium lasers are Er:YAG lasers.

11. (Currently Amended) A medical laser comprising:

a. a laser source having two or more pulsed lasers for generating pulses of laser light having a wavelength, wherein a series of the pulses of laser light are combined from the laser source for generating a single laser output having a predetermined absorption, wherein the predetermined absorption forms a predetermined coagulation depth; and

b. a laser control system coupled to the laser source for controlling the laser source to deliver the laser output to a target area.

12. (Original) The medical laser as claimed in claim 11 further comprising a graphical user interface through which a user selects a depth of the coagulation region formed by the coagulative laser pulses.

13. (Original) The medical laser as claimed in claim 12 further comprising a laser delivery system coupled to the laser source for delivering the laser beam from the laser source to an area of tissue to be treated.

14. (Original) The medical laser as claimed in claim 13 wherein the laser delivery system comprises an articulated arm and one or more refocussing optics for refocussing the laser beam as it travels through the arm.

Claims 15-16 (Canceled).

17. (Currently Amended) A medical laser delivery apparatus for treating an area of tissue comprising:

a. a laser source having a first laser and a second laser each of which generate laser pulses having a wavelength, the laser source being configured to combine laser pulses of the first laser and the second laser to form a single laser output by a combining apparatus for delivering a series of laser pulses each having a strength and a duration to ablate or coagulate the area of tissue being treated;

b. a laser delivery system coupled to the laser source for delivering the laser pulses from the laser source to the area of tissue being treated; and

c. a control system for selecting the rate and fluence of the laser pulses, the control system coupled to the laser source for controlling generation of the laser pulses from the laser source, wherein the laser source operates in both an ablation mode and a coagulation mode such that when in the ablation mode, the strength and duration of the laser pulses are sufficient to ablate tissue at the area of tissue being treated to a controllable ablation depth and when in the coagulation mode, the strength and duration of the laser pulses are sufficient to generate a coagulation region having a controllable coagulation depth within the tissue remaining at the area of tissue being treated without ablating any tissue.

18. (Original) The medical laser delivery apparatus as claimed in claim 17 further comprising a graphical user interface through which a user selects the controllable ablation depth and the controllable coagulation depth.

19. (Original) The medical laser delivery apparatus as claimed in claim 18 wherein the laser delivery system comprises an articulated arm and one or more refocussing optics for refocussing the laser beam as its travels through the articulated arm.

20. (Original) The medical laser delivery apparatus as claimed in claim 19 wherein the laser delivery system further comprises a scanning handpiece at an end of the arm for providing the laser pulses to the area of tissue being treated.

21. (Original) The medical laser delivery apparatus as claimed in claim 20 wherein the refocussing optics are simple convex lenses.

22. (Original) The medical laser delivery apparatus as claimed in claim 21 wherein the laser source includes a laser having a short penetration depth.

23. (Previously Presented) The medical laser delivery apparatus as claimed in claim 22, wherein the first and second lasers are erbium lasers.

24. (Previously Presented) The medical laser delivery apparatus as claimed in claim 23 wherein the erbium lasers are Er:YAG lasers.

Claims 25-40 (Canceled)

41. (Currently Amended) A dual mode medical laser system, for sequentially ablating and coagulating a region of target tissue with ablation laser pulses followed by coagulation laser pulses, the dual mode medical laser system comprising:

a. a laser source comprising a first laser and a second laser for generating a first set of laser pulses and a second set of laser pulses at a wavelength;

b. means to combine pulses of the first set of laser pulses and the second set of laser pulses to provide a single laser output, the single laser output being capable of coagulating tissue with the system in a coagulation mode and ablating tissue with the system in an ablating mode; and

c. means to direct the single laser output to the region of the target tissue.

42. (Original) The dual mode medical laser system of claims 41 wherein the first laser and the second laser are Er:YAG lasers.

43. (Previously Presented) The dual mode medical laser system of claim 41 wherein the means to combine pulses of the first set of laser pulses and the second set of laser pulses is a galvanometer.

44. (Original) The dual mode medical laser system of claim 41 further comprising a user interface, wherein a user selects an ablation depth and a coagulation depth and wherein a series of the ablation laser pluses with a fluence corresponding to the selected ablation depth are generated followed by a series of the coagulation laser pulses with a fluence corresponding to the selected coagulation depth.

45. (Original) The dual mode medical laser system of claim 44 wherein the user interface comprises a mode selector for selecting between manual mode and scan mode, wherein the user further selects a scan size and a laser pulse pattern with the scan mode selected.

46. (Original) The dual mode medical laser system of claim 45 wherein the user interface is a graphical user interface for displaying the selected laser pulse pattern.

47. (Original) The dual mode medical laser system of claim 41 wherein the ablation laser pulses have a duration of approximately 500 microseconds and a fluence of approximately 2 Joules/cm^2.

48. (Previously Presented) The dual mode medical laser system of claim 41 wherein when the system is in the coagulation mode, the coagulation laser pulses of the first set of laser pulses and the second set of laser pulses each have a duration of approximately 150 microseconds and a combined fluence of approximately 200 milliJoules/cm^2.

49. (Original) The dual mode medical laser system of claim 41 wherein the means to direct the single laser output to the region of the target tissue comprises an articulated arm

feature with a plurality of refocussing lenses for guiding and focussing the single laser output through the articulated arm feature.

50. (New) A medical laser delivery apparatus for delivering a series of laser pulses having a wavelength, the medical laser delivery apparatus including non-ablative laser pulses for directing to an area of tissue to be treated and generating a region of coagulation to a controllable coagulation depth under a surface of the area of tissue, the apparatus comprising a laser source for generating the series of laser pulses including the non-ablative laser pulses to be delivered to the area of tissue to be treated in order to raise a temperature at the surface of the area of tissue to be treated to a temperature sufficient to generate coagulation at the coagulation depth when the laser source is in a coagulation mode, wherein the laser source comprises two or more lasers, the medical laser delivery apparatus further comprising a galvanometer that combines the series of laser pulses from the two or more lasers into a single laser output by switching between laser outputs from the two or more lasers.

51. (New) A medical laser comprising:

a. a laser source having two or more pulsed lasers for generating laser outputs having a wavelength, wherein a series of the pulses of laser light are combined into a single laser output by switching between the laser outputs with a galvanometer, the single laser output having a predetermined absorption, wherein the predetermined absorption forms a predetermined coagulation depth; and

b. a laser control system coupled to the laser source for controlling the laser source to deliver the laser output to a target area.

REMARKS

The Applicants respectfully request further examination and reconsideration in view of the amendments set forth above and the arguments set forth below. Claims 1-14, 17-24 and 41-49 were pending in this application. Within the previous Office Action, Claims 1-14, 17-24 and 41-49 have all been rejected. By way of the above amendment, Claims 1, 11, 17 and 41 been amended and new Claims 50 and 51 have been added. Accordingly, Claims 1-14, 17-24 and 41-51 are now pending in this application.

Rejections Under 35 U.S.C. § 112

Applicants acknowledge that the rejections of Claims 1-14 under 35 U.S.C. 112, first paragraph, cited in the previous Office Action have been withdrawn.

Rejections Under 35 U.S.C. § 102

Within the Office Action, Claims 1, 11, 17 and 41 have been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,125,922 to Dwyer (hereafter "Dwyer"). Specifically, it is stated within the Office Action that Dwyer teaches two lasers whose outputs are combined at a beam splitter. [Dwyer: Figure 3 and Column 4, lines 12-22]

Regarding Claim 17, the Office Action appears to suggest that the function of the control system is not clearly stated in relation to the other elements that are also recited in the Claim 17 and, therefore, the recitation of the control system is afforded little weight in determining the patentability of this claim.

Regarding Claim 41, it is stated within the Office Action that Dwyer teaches means to alternate between pluses of a first set and a second set of pulses, presumably by manually turning on and of off selected lasers. [Dwyer; Column 4, lines 20-22]

Within the Office Action, it is further stated that the Applicant's arguments have been presented without pointing to specific structural features that are lacking in Dwyer and this Office Action has been made final.

Applicants respectfully traverse these rejections for the following reason. The claims pending in the present application recite features and functions that are distinct and patentable over the teachings of Dwyer. Dwyer teaches an apparatus with two lasers producing two different wavelengths. An operator can choose which wavelength is selected by turning on the appropriate laser and shutting off the appropriate laser. However, it not feasible to alternate

between pulses or sets of pulses in the time frame required to perform a coagulation or ablation operation on a target area tissue as recited in the claims of the present invention. The present invention is directed to a laser system that alternates between pulses of two lasers having a wavelength. This enables the laser system of the present invention to perform any number of selectable operations, most notable which are coagulation and ablation to a target area of tissue, without requiring multiple laser systems. Dwyer clearly does not teach these features. Nevertheless in order to further advance the prosecution of this application, Claims 1, 11, 17 and 41 have now been amended to further define these features. Claim 17 has also been amended to recite specific functions of the control system in relation to other elements claimed.

Specifically, the independent Claim 1 is directed to a medical laser delivery apparatus for delivering a series of laser pulses having a wavelength, the medical laser delivery apparatus including non-ablative laser pulses for directing to an area of tissue to be treated and generating a region of coagulation to a controllable coagulation depth under a surface of the area of tissue. The apparatus comprises a laser source for generating the series of laser pulses including the non-ablative laser pulses to be delivered to the area of tissue to be treated in order to raise a temperature at the surface of the area of tissue to be treated to a temperature sufficient to generate coagulation at the coagulation depth when the laser source is in a coagulation mode. The laser source comprises two or more lasers that combine the series of laser pulses from the two or more lasers. As discussed above, Dwyer fails to teach a medical laser delivery apparatus which has a laser source with two or more lasers having a wavelength that are combined to form a single output to generate conditions for ablation and coagulation. For at least these reasons, the independent Claim 1 is allowable over the teachings of Dwyer.

The independent Claim 11 is directed to a medical laser comprising a laser source having two or more pulsed lasers for generating pulses of laser light having a wavelength, wherein a series of the pulses of laser light are combined from the laser source for generating a single laser output having a predetermined absorption, wherein the predetermined absorption forms a predetermined coagulation depth and a laser control system coupled to the laser source for controlling the laser source to deliver the laser output to a target area. As discussed above, Dwyer fails to teach a medical laser delivery apparatus which has a laser source with two or more lasers having a wavelength that are combined to form a single output to generate conditions for ablation and coagulation. For at least these reasons, the independent Claim 11 is allowable over the teachings of Dwyer.

The independent Claim 17 is directed to a medical laser delivery apparatus for treating an area of tissue, the laser delivery apparatus comprising source having a first laser and a second laser each of which generates laser pulses having a wavelength, the laser source being configured to combine laser pulses of the first laser and the second laser to form a single laser output by a combining apparatus for delivering a series of laser pulses each having a strength and a duration to ablate or coagulate the area of tissue being treated, a laser delivery system coupled to the laser source for delivering the laser pulses from the laser source to the area of tissue being treated, and a control system for selecting the rate and fluence of the laser pulses, the control system coupled to the laser source for controlling generation of the laser pulses from the laser source, wherein the laser source operates in both an ablation mode and a coagulation mode such that when in the ablation mode, the strength and duration of the laser pulses are sufficient to ablate tissue at the area of tissue being treated to a controllable ablation depth and when in the coagulation mode, the strength and duration of the laser pulses are sufficient to generate a coagulation region having a controllable coagulation depth within the tissue remaining at the area of tissue being treated without ablating any tissue. As discussed above, Dwyer fails to teach a medical laser delivery apparatus which has a laser source with two or more lasers having a wavelength that are combined to form a single output to generate conditions for ablation and coagulation. For at least these reasons, the independent Claim 17 is allowable over the teachings of Dwyer.

The independent Claim 41 is directed to a dual mode medical laser system, for sequentially ablating and coagulating a region of target tissue with ablation laser pulses followed by coagulation laser pulses. The dual mode medical laser system comprises a laser source comprising a first laser and a second laser for generating a first set of laser pulses and a second set of laser pulses at a wavelength, means to combine pulses of the first set of laser pulses and the second set of laser pulses to provide a single laser output, the single laser output being capable of coagulating tissue with the system in a coagulation mode and ablating tissue with the system in an ablating mode and means to direct the single laser output to the region of the target tissue. As discussed above, Dwyer fails to teach a system capable of coagulating tissue with the system in a coagulation mode, and ablating tissue with the system in ablation mode which combines laser pulses having a wavelength from multiple lasers to generate a single laser output. For at least these reasons, the independent Claim 41 is allowable over the teachings of Dwyer.

Rejections Under 35 U.S.C. § 103

Within the Office Action, Claims 1-3, 8, 41, 43, 44 and 47-49 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,672,969 to Dew (hereinafter "Dew") in combination with, U.S. Patent No. 5,620,435 to Belkin et al. (hereinafter "Belkin") and, the article entitled "Selective Photothermolysis: Precise Microsurgery by Selective Absorption of Pulsed Radiation" by R. Rox Anderson and John A. Parrish (hereinafter "Anderson et al.").

The teachings of Dew, Belkin et al. and Anderson et al. have all been fully characterized in previous communications. In summary, neither Dew, Belkin, Anderson et al., nor their combination teach or suggest combining laser pulses from a laser source comprising two or more lasers having a wavelength to generate a single laser output for coagulating or ablating tissue. These features as well as other distinguishing features are recited in the independent Claims 1 and 41. For at least these reasons, the independent Claims 1 and 41 are allowable over the teachings of Dew, Belkin et al., Anderson et al. and their combination.

Claims 2, 3 and 8 are all dependent on the independent Claim 1. As described above, the independent Claim 1 is allowable over the teachings of Dew, Belkin et al., Anderson et al. and their combination. Accordingly, Claims 2, 3 and 8 are all also allowable as being dependent upon an allowable base claim.

Claims 43, 44 and 47-49 are all dependent on the independent Claim 41. As described above, the independent Claim 41 is allowable over the teachings of Dew, Belkin et al., Anderson et al. and their combination. Accordingly, Claims 43, 44 and 47-49 are also all allowable as being dependent upon an allowable base claim.

Within the Office Action, Claims 1, 6, 7, 11-13, 17, 18, 41 and 44-46 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,098,426 to Sklar et al. (hereinafter "Sklar") in combination with Dwyer.

Sklar has been full characterized in previous communications. In summary, neither Sklar, Dwyer nor their combination teaches or suggests combining laser pulses from a laser source comprising two or more lasers having a wavelength to generate a single laser output for coagulating or ablating tissue. These features, as well as other distinguishing features, are recited in the independent Claims 1, 11, 17 and 41. For at least these reasons, the independent Claims 1, 11, 17 and 41 are allowable over the teachings of Sklar, Dwyer and their combination.

Claims 6 and 7 are both dependent on the independent Claim 1. As described above, the independent Claim 1 is allowable over the teachings of Sklar, Dwyer and their combination.

Accordingly, Claims 6 and 7 are both also allowable as being dependent upon an allowable base claim.

Claims 12 and 13 are both dependent on the independent Claim 11. As described above, the independent Claim 11 is allowable over the teachings of Sklar, Dwyer and their combination. Accordingly, Claims 12 and 13 are also both allowable as being dependent upon an allowable base claim.

Claim 18 is dependent on the independent Claim 17. As described above, the independent Claim 17 is allowable over the teachings of Sklar, Dwyer and their combination. Accordingly, Claim 18 is also allowable as being dependent upon an allowable base claim.

Claims 44-46 are all dependent on the independent Claim 41. As described above, the independent Claim 41 is allowable over the teachings of Sklar, Dwyer and their combination. Accordingly, Claims 44-46 are also all allowable as being dependent upon an allowable base claim.

Within the Office Action, Claims 4, 9, 10 and 42 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Dew in combination with Anderson et al., Belkin et al. and further in view of U.S. Patent No. 5,938,657 to Assa et al. (hereafter "Assa et al.").

The teachings of Assa have been fully characterized previously. Neither Dew, Anderson, Belkin et al., Assa et al. nor their combination teaches or suggests combining laser pulses from a laser source comprising two or more lasers having a wavelength to generate a single laser output for coagulating or ablating tissue such as recited in the independent Claims 1 and 41.

Claims 4, 9, and 10 are all dependent on the independent Claim 1, and Claim 42 is dependent on the independent Claim 41. As described above, the independent Claims 1 and 41 are both allowable over the teachings Dew, Belkin, Anderson et al. and their combination. Accordingly, Claims 4, 9, 10 and 41 are also all allowable as being dependent upon allowable base claims.

Within the Office Action, Claims 14 and 19-22 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Dew in combination with Anderson et al. and Belkin et al. and further in view of Sklar.

As previously described neither Anderson et al., Belkin et al., Sklar nor their combination teach or suggest combining laser pulses from a laser source comprising two or more lasers having a wavelength to generate a single laser output for coagulating or ablating tissue such as recited in the independent Claim 11.

Claims 14 and 19-22 are all dependent on the independent Claim 11. As described above the independent Claim 11 is allowable over the teaching of Sklar, Dwyer and their combination. Accordingly, Claims 14 and 19-22 are also all allowable as being dependent on an allowable base claim.

Within the Office Action, Claims 23 and 24 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Dew in combination with Anderson et al., Belkin et al., Sklar and further in view of Assa et al.

Again, neither Dew, Anderson et al., Belkin et al., Sklar, Assa et al., nor their combination teaches or suggests combining laser pulses from a laser source comprising two or more lasers having a wavelength to generate a single laser output for coagulating or ablating tissue such as recited in the independent Claim 17.

Claims 23 and 24 are both dependent on the independent Claim 17. As described above, the independent Claim 17 is allowable over the teachings of Sklar, Dwyer and their combination. Accordingly, Claims 23 and 24 are both also allowable as being dependent upon an allowable base claim.

New Claims:

By way of the above amendment, new Claims 50 and 51 have been added. The new Claims 50 and 51 recite the limitations of Claims 1 and 11, respectively. Claims 50 and 51 further recite that pulses from multiple laser outputs are combined into a single laser output with a galvanometer that switches between the multiple laser outputs. These features find support in the original specification as originally filed at least at page 7, lines 13-15.

Lastly, the Applicants contend the issuance of a Final Office Action was premature. In a response to the previous Office Action, Applicant filed an RCE with amendments to the claims, which included limitations which were not addressed in any previous Office Action and which Applicants contend could not be properly rejected on the art made of record. Accordingly, the Applicants respectfully request that the above amendments be entered and the Finality of the Office Action be withdrawn.

For the reasons given above, Applicants respectfully submit that the claims are in a condition for allowance, and allowance at an early date would be appreciated. Should the Examiner have any questions or comments, he is encouraged to call the undersigned at (408) 530-9700 to discuss them so that any outstanding issues can be expeditiously resolved.

Respectfully submitted,
HAVERSTOCK & OWENS LLP

Dated: July 14, 2004 By: Jonathan O. Owens

Jonathan O. Owens
Reg. No.: 37,902
Attorneys for Applicant

CERTIFICATE OF MAILING (37 CFR§ 1.8(a))

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the U.S. Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the: Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450

HAVERSTOCK & OWENS LLP

Date: 7-14-04 By:

PATENT
Attorney Docket No.: SCI-00100

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Group Art Unit: 3739
	Examiner: Shay, D.
James L. Hobart *et al.*	
	REQUEST FOR A ONE MONTH EXTENSION OF TIME
Serial No.: 09/018,104	
Filed: February 3, 1998	162 North Wolfe Road Sunnyvale, CA 94086 (408)530-9700
For: **DUAL MODE LASER DELIVERY SYSTEM PROVIDING CONTROLLABLE DEPTH OF TISSUE ABLATION AND CORRESPONDING CONTROLLABLE DEPTH OF COAGULATION**	Customer Number 28960

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants hereby petition for a one month extension of time to answer the outstanding Final Office Action mailed July 28, 2003 regarding the above-identified patent application. Please find a check enclosed in the amount of $440.00 to cover the $385.00 Request for Continued Examination filing fee plus $55.00 for a one month extension of time fee.

Respectfully submitted,
HAVERSTOCK & OWENS LLP

Dated: November 28, 2003

By: Jonathan O. Owens
Jonathan O. Owens
Reg. No.: 37,902

Attorneys for Applicants

CERTIFICATE OF MAILING (37 CFR § 1.8(a))
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HAVERSTOCK & OWENS LLP
Date: 11-28-03 By:

PATENT
Attorney Docket No.: SCI-00100

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Group Art Unit: 3739
James L. Hobart et al.	Examiner: Shay, D.
Serial No.: 09/018,104	
Filed: February 3, 1998	
For: **DUAL MODE LASER DELIVERY SYSTEM PROVIDING CONTROLLABLE DEPTH OF TISSUE ABLATION AND CORRESPONDING CONTROLLABLE DEPTH OF COAGULATION**	**PRELIMINARY AMENDMENT**
	162 North Wolfe Road Sunnyvale, California 94086 (408) 530-9700
	Customer No.: 28960

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir/Madam:

AMENDMENTS

Please Amend the above referenced Application as follows:

Amendments to the claims:

Please replace all prior versions and listings of the claims with the following amended claims:

1. (Currently Amended) A medical laser delivery apparatus for delivering a series of laser pulses including non-ablative laser pulses to an area of tissue to be treated and generating a region of coagulation to a controllable coagulation depth under a surface of the area of tissue, the apparatus comprising a laser source for generating the series of laser pulses including the non-ablative laser pulses to be delivered to the area of tissue to be treated in order to raise a temperature at the surface of the area of tissue to be treated to a temperature sufficient to generate coagulation at the coagulation depth when the laser source is in a coagulation mode, wherein the laser source comprises two or more lasers

that combines the series of laser pulses from the two or more lasers~~, each for generating laser pulses to provide the series of laser pulses and sufficient to generate ablation~~ when the laser source is in an ablation mode.

2. (Previously Presented) The medical laser delivery apparatus as claimed in claim 1 wherein the series of laser pulses are focussed to the target tissue through an articulated arm feature.

3. (Previously Presented) The medical laser delivery apparatus as claimed in claim 2 wherein the articulated arm feature comprises one or more refocussing optics for refocussing the laser pulses as they travel through the articulated arm feature.

4. (Previously Presented) The medical laser delivery apparatus as claimed in claim 3 wherein the laser delivery system further comprises a scanning handpiece at an end of the articulated arm feature for guiding the series of one or more non-ablative laser pulses to the area of tissue being treated.

6. (Original) The medical laser delivery apparatus as claimed in claim 1 further comprising a graphical user interface through which a user selects the coagulation depth and/or fluence.

7. (Original) The medical laser delivery apparatus as claimed in claim 6 wherein the laser source also has an ablation mode wherein it generates laser pulses of a strength and duration to ablate tissue at the area of tissue being treated to an ablation depth and the user selects the ablation depth through the graphical user interface.

8. (Previously Presented) The medical laser delivery apparatus as claimed in claim 1 wherein the apparatus is configured to generate laser pulses with short penetration depths.

9. (Previously Presented) The medical laser delivery apparatus as claimed in claim 8 wherein the two or more lasers are erbium lasers.

10. (Previously Presented) The medical laser delivery apparatus as claimed in claim 9 wherein the erbium lasers are Er:YAG lasers.

11. (Currently Amended) A medical laser comprising:

a. a laser source having two or more pulsed lasers for generating pulses of laser light, wherein ~~the~~ a series of the pulses of laser light are combined from the laser source ~~in an alternating fashion~~ for generating a single laser output having a predetermined absorption, wherein the predetermined absorption forms a predetermined coagulation depth; and

b. a laser control system coupled to the laser source for controlling the laser source to deliver the laser output to a target area.

12. (Original) The medical laser as claimed in claim 11 further comprising a graphical user interface through which a user selects a depth of the coagulation region formed by the coagulative laser pulses.

13. (Original) The medical laser as claimed in claim 12 further comprising a laser delivery system coupled to the laser source for delivering the laser beam from the laser source to an area of tissue to be treated.

14. (Original) The medical laser as claimed in claim 13 wherein the laser delivery system comprises an articulated arm and one or more refocussing optics for refocussing the laser beam as it travels through the arm.

Claims 15-16 (Canceled).

17. (Currently Amended) A medical laser delivery apparatus for treating an area of tissue comprising:

a. a laser source having a first laser and a second laser each of which generate laser pulses having a wavelength, the laser source being configured to ~~alternate between~~ combine laser pulses of the first laser and the second laser to form a single laser output by a combining apparatus for ~~generating~~ delivering a series of laser pulses

each having a strength and a duration to ablate or coagulate the area of tissue being treated;

b. a laser delivery system coupled to the laser source for delivering the laser pulses from the laser source to the area of tissue being treated; and

c. a control system coupled to the laser source for controlling generation of the laser pulses from the laser source, wherein the laser source operates in both an ablation mode and a coagulation mode such that when in the ablation mode, the strength and duration of the laser pulses are sufficient to ablate tissue at the area of tissue being treated to a controllable ablation depth and when in the coagulation mode, the strength and duration of the laser pulses are sufficient to generate a coagulation region having a controllable coagulation depth within the tissue remaining at the area of tissue being treated without ablating any tissue.

18. (Original) The medical laser delivery apparatus as claimed in claim 17 further comprising a graphical user interface through which a user selects the controllable ablation depth and the controllable coagulation depth.

19. (Original) The medical laser delivery apparatus as claimed in claim 18 wherein the laser delivery system comprises an articulated arm and one or more refocussing optics for refocussing the laser beam as its travels through the articulated arm.

20. (Original) The medical laser delivery apparatus as claimed in claim 19 wherein the laser delivery system further comprises a scanning handpiece at an end of the arm for providing the laser pulses to the area of tissue being treated.

21. (Original) The medical laser delivery apparatus as claimed in claim 20 wherein the refocussing optics are simple convex lenses.

22. (Original) The medical laser delivery apparatus as claimed in claim 21 wherein the laser source includes a laser having a short penetration depth.

23. (Previously Presented) The medical laser delivery apparatus as claimed in claim 22, wherein the first and second lasers are erbium lasers.

24. (Previously Presented) The medical laser delivery apparatus as claimed in claim 23 wherein the erbium lasers are Er:YAG lasers.

Claims 25-40 (Canceled)

41. (Currently Amended) A dual mode medical laser system, for sequentially ablating and coagulating a region of target tissue with ablation laser pulses followed by coagulation laser pulses, the dual mode medical laser system comprising:

a. a laser source comprising a first laser and a second laser for generating a first set of laser pulses and a second set of laser pulses;

b. means to ~~alternate between~~ combine pulses of the first set of laser pulses and the second set of laser pulses to provide a single laser output, the single laser output being capable of coagulating tissue with the system in a coagulation mode and ablating tissue with the system in an ablating mode; and

c. means to direct the single laser output to the region of the target tissue.

42. (Original) The dual mode medical laser system of claims 41 wherein the first laser and the second laser are Er:YAG lasers.

43. (Currently Amended) The dual mode medical laser system of claim 41 wherein the means to ~~alternate between~~ combine pulses of the first set of laser pulses and the second set of laser pulses ~~the first laser beam and the second laser beam~~ is a galvanometer.

44. (Original) The dual mode medical laser system of claim 41 further comprising a user interface, wherein a user selects an ablation depth and a coagulation depth and wherein a series of the ablation laser pluses with a fluence corresponding to the selected ablation depth are generated followed by a series of the coagulation laser pulses with a fluence corresponding to the selected coagulation depth.

45. (Original) The dual mode medical laser system of claim 44 wherein the user interface comprises a mode selector for selecting between manual mode and scan mode, wherein the user further selects a scan size and a laser pulse pattern with the scan mode selected.

46. (Original) The dual mode medical laser system of claim 45 wherein the user interface is a graphical user interface for displaying the selected laser pulse pattern.

47. (Original) The dual mode medical laser system of claim 41 wherein the ablation laser pulses have a duration of approximately 500 microseconds and a fluence of approximately 2 Joules/cm^2.

48. (currently amended) The dual mode medical laser system of claim 41 wherein when the system is in the coagulation mode, the coagulation laser pulses of the first set of laser pulses and the second set of laser pulses each have a duration of approximately 150 microseconds and a combined fluence of approximately 200 milliJoules/cm^2.

49. (Original) The dual mode medical laser system of claim 41 wherein the means to direct the single laser output to the region of the target tissue comprises an articulated arm feature with a plurality of refocussing lenses for guiding and focussing the single laser output through the articulated arm feature.

REMARKS

The Applicant respectfully requests further examination and reconsideration in view of the arguments set forth below. Claims 1-14, 17-24 and 41-49 were pending in this application. Within the previous Office Action, Claims 1-14, 17-24 and 41-49 have all been rejected. By way of the above amendment, Claims 1, 11, 17, 41 and 43 have been amended. Accordingly, Claims 1-14, 17-24 and 41-49 are still pending in this application.

Rejections Under 35 U.S.C. § 112

Claims 1-14 have been rejected under 35 U.S.C. 112, first paragraph, for containing subject matter which was not described in the specification in such a way as to convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

It is stated within the previous Office Action that the disclosure of the instant Application provides support for use of two lasers and support for combining two laser beams. However, it is further stated within the previous Office Action that there is insufficient teaching in the disclosure of the Application to support claim language that recites laser pulses that are combined, wherein each of the laser pulses produce ablation pulses. The Applicant respectfully disagrees for the following reasons.

Throughout the specification of the instant Application that the Applicants refer to a system with a "laser source" and that the laser source comprises "two or more lasers" for operating in ablation mode and coagulation mode. Applicants further state that "ablation mode combines a series of one or more pulses from the laser source." [Specification, Page 11, line 2] Applicant contends that the word "combines" is used herein to denote its common meaning which is to unite, join forces for a single purpose or otherwise make a union of two or more things, in this case laser pulses from two or more lasers. Further, Applicants contend that it would be clear to one skilled in the art that the language "combines pulses" means to combine pulses from the two or more lasers of the laser source to form a single laser output and generate a single operative condition for ablating tissue and coagulating tissue when the system is operating in ablation mode or coagulation mode, respectively. Additional support for a laser system that operates with a single laser output using multiple lasers beams have been presented in a previous communication.

While the Applicant disagrees with the rejection of the claim 1-14 under 35 U.S.C. 112, first paragraph, in order to further the prosecution of the Application, Claims 1 and 11 have been amended to recite claim language which comports with language used in the specification and which clearly supports combining laser pulses from a laser source with multiple lasers to generate a condition for ablation.

The independent Claim 1 now recites medical laser delivery apparatus for delivering a series of laser pulses including non-ablative laser pulses to an area of tissue to be treated and generating a region of coagulation to a controllable coagulation depth under a surface of the area of tissue, the apparatus comprising a laser source for generating the series of laser pulses including the non-ablative laser pulses to be delivered to the area of tissue to be treated in order to raise a temperature at the surface of the area of tissue to be treated to a temperature sufficient to generate coagulation at the coagulation depth when the laser source is in a coagulation mode, wherein the laser source comprises two or more lasers that combines the series of laser pulses from the two or more lasers, when the laser source is in an ablation mode. As discussed above, the independent Claim 1 finds clear support for the recitation of a laser source that comprises two or more lasers that combines a series of laser pulses from the laser source, when the laser source is in an ablation mode.

The independent Claim 11 recites a medical laser comprising a laser source having two or more pulsed lasers for generating pulses of laser light, wherein a series of the pulses of laser light are combined from the laser source for generating a single laser output having a predetermined absorption, wherein the predetermined absorption forms a predetermined coagulation depth and a laser control system coupled to the laser source for controlling the laser source to deliver the laser output to a target area. As discussed above, the independent Claim 11 finds clear support for the recitation of a laser source with two or more pulsed lasers that generate pluses that are combined in the above quoted passage and throughout the originally filed specification.

Claims 2-10 are all dependent from the independent Claim 1 and Claims 12-14 are all dependent from the independent Claim 11. For all of the reasons stated above, rejection of Claims 1-14 under 35 U.S.C. 112, first paragraph is not appropriate and should be withdrawn.

Rejections Under 35 U.S.C. § 102

Within the previous Office Action, Claims 17 and 41 have been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,125,922 to Dwyer (hereafter "Dwyer"). The Applicants respectfully traverse this rejection. Dwyer fails to teach a system with a laser source

having multiple lasers, wherein pulses from the laser source are combined to generate a single laser output or a single operative condition such as coagulation or ablation, when the system is in coagulation mode or ablation mode, respectively. The teachings of Dwyer have been fully characterized in a previous commination.

Briefly, Dwyer teaches a laser device that switches between two laser conditions but fails to teach or suggest combining laser pulses. In contrast to the teachings of Dwyer, the instant invention is directed to a laser system that is capable of operating in an ablation mode and a coagulation mode by using a laser source with two or more lasers, wherein pulses of the lasers are combined to generate a single laser output or a single operative mode. No where in the prior art are the features of combining a series of pulses to generate a single laser output or operative conditions taught or suggested. These and other features are clearly recited in the independent Claims 17 and 41.

Specifically, the independent Claim 17 is directed to a medical laser delivery apparatus for treating an area of tissue comprising a laser source having a first laser and a second laser each of which generate laser pulses having a wavelength, the laser source being configured to combine laser pulses of the first laser and the second laser to form a single laser output by a combining apparatus for delivering a series of laser pulses each having a strength and a duration to ablate or coagulate the area of tissue being treated. The medical laser delivery apparatus of Claim 17 also comprises a laser delivery system coupled to the laser source for delivering the laser pulses from the laser source to the area of tissue being treated and a control system coupled to the laser source for controlling generation of the laser pulses from the laser source, wherein the laser source operates in both an ablation mode and a coagulation mode such that when in the ablation mode, the strength and duration of the laser pulses are sufficient to ablate tissue at the area of tissue being treated to a controllable ablation depth and when in the coagulation mode, the strength and duration of the laser pulses are sufficient to generate a coagulation region having a controllable coagulation depth within the tissue remaining at the area of tissue being treated without ablating any tissue. As discussed above, Dwyer fails to teach a medical laser delivery apparatus which has a laser source with a first laser and a second laser that combines lasers pulses to form a single output to generate conditions for ablation and coagulation. For at least these reasons, the independent Claim 17 is allowable over the teachings of Dwyer.

The independent Claim 41 is directed to a dual mode medical laser system, for sequentially ablating and coagulating a region of target tissue with ablation laser pulses followed by coagulation laser pulses, the dual mode medical laser system comprising a laser source

comprising a first laser and a second laser for generating a first set of laser pulses and a second set of laser pulses, means to combine pulses of the first set of laser pulses and the second set of laser pulses to provide a single laser output, the single laser output being capable of coagulating tissue with the system in a coagulation mode and ablating tissue with the system in an ablating mode and means to direct the single laser output to the region of the target tissue. As discussed above Dwyer fails to teach a system capable of coagulating tissue with the system in a coagulation mode and ablating tissue with the system in ablation mode which combines laser pulses from multiple lasers to generate a single laser output. For at least these reasons, the independent Claim 41 is allowable over the teachings of Dwyer.

Rejections Under 35 U.S.C. § 103

Within the previous Office Action, Claims 1-3, 6-8, 11-14, 17-19, 41 and 43-49 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,098,426 to Sklar et al. (hereinafter "Sklar") in combination with U.S. Patent No. 4,672,969 to Dew (hereinafter "Dew"), U.S. Patent No. 5,620,435 to Belkin et al. (hereinafter "Belkin") and, the article entitled "Selective Photothermolysis: Precise Microsurgery by Selective Absorption of Pulsed Radiation" by R. Rox Anderson and John A. Parrish (hereinafter "Anderson") and U.S. Patent No. 5,125,922 to Dwyer (hereinafter "Dwyer"). The Applicant respectfully traverses this rejection.

The teachings of Sklar, Dew, Belkin, Anderson and Dwyer have all been fully characterized in previous communications. In summary none of the references cited teach or suggest combining laser pulses from a laser source comprising two or more lasers to generate a single laser output for coagulating or ablating tissue. These features as well as other distinguishing features are recited in the independent Claims 1, 11, 17 and 41.

The independent Claim 1 is directed to medical laser delivery apparatus for delivering a series of laser pulses including non-ablative laser pulses to an area of tissue to be treated and generating a region of coagulation to a controllable coagulation depth under a surface of the area of tissue, the apparatus comprising a laser source for generating the series of laser pulses including the non-ablative laser pulses to be delivered to the area of tissue to be treated in order to raise a temperature at the surface of the area of tissue to be treated to a temperature sufficient to generate coagulation at the coagulation depth when the laser source is in a coagulation mode, wherein the laser source comprises two or more lasers that combines the series of laser pulses from the two or more lasers, when the laser source is in an ablation mode. As discussed above,

neither Sklar, Dew, Belkin, Anderson, Dwyer nor their combination teach or make obvious a laser system comprising a laser source with two or more lasers that combines a series of laser pulses from the two or more lasers when the laser source is in an ablation mode. For at least these reasons, the independent Claim 1 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination.

Claims 2, 3 and 6-8 are all dependent on the independent Claim 1. As described above, the independent Claim 1 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination. Accordingly, Claims 2, 3 and 6-8 are all also allowable as being dependent upon an allowable base claim.

The independent Claim 11 is directed to a medical laser comprising a laser source having two or more pulsed lasers for generating pulses of laser light, wherein a series of the pulses of laser light are combined from the laser source for generating a single laser output having a predetermined absorption, wherein the predetermined absorption forms a predetermined coagulation depth and a laser control system coupled to the laser source for controlling the laser source to deliver the laser output to a target area. As discussed above, neither Sklar, Dew, Belkin, Anderson, Dwyer nor their combination teach or make obvious a medical laser, wherein pulses of laser light are combined from the laser source for generating a single laser output. For at least these reasons, the independent Claim 11 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination.

Claims 12-14 are all dependent on the independent Claim 11. As described above, the independent Claim 11 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination. Accordingly, Claims 12-14 are all also allowable as being dependent upon an allowable base claim.

The independent Claim 17 is directed to medical laser delivery apparatus for treating an area of tissue comprising a laser source having a first laser and a second laser each of which generate laser pulses having a wavelength, the laser source being configured to combine laser pulses of the first laser and the second laser to form a single laser output by a combining apparatus for delivering a series of laser pulses each having a strength and a duration to ablate or coagulate the area of tissue being treated. The medical laser delivery apparatus of Claim 17 comprises a laser delivery system coupled to the laser source for delivering the laser pulses from

the laser source to the area of tissue being treated and a control system coupled to the laser source for controlling generation of the laser pulses from the laser source, wherein the laser source operates in both an ablation mode and a coagulation mode such that when in the ablation mode, the strength and duration of the laser pulses are sufficient to ablate tissue at the area of tissue being treated to a controllable ablation depth and when in the coagulation mode, the strength and duration of the laser pulses are sufficient to generate a coagulation region having a controllable coagulation depth within the tissue remaining at the area of tissue being treated without ablating any tissue. As discussed above, neither Sklar, Dew, Belkin, Anderson, Dwyer nor their combination teach or make obvious a medical laser delivery apparatus which has a laser source with two or more lasers that combines lasers pulses to generate conditions for ablation and coagulation. For at least these reasons, the independent Claim 17 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination.

Claims 18 and 19 are both dependent on the independent Claim 17. As described above, the independent Claim 17 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination. Accordingly, Claims 18 and 19 are both allowable as being dependent upon an allowable base claim.

The independent Claim 41 is directed to a dual mode medical laser system, for sequentially ablating and coagulating a region of target tissue with ablation laser pulses followed by coagulation laser pulses, the dual mode medical laser system comprising a laser source comprising a first laser and a second laser for generating a first set of laser pulses and a second set of laser pulses, means to combine pulses of the first set of laser pulses and the second set of laser pulses to provide a single laser output, the single laser output being capable of coagulating tissue with the system in a coagulation mode and ablating tissue with the system in an ablating mode; and means to direct the single laser output to the region of the target tissue. As discussed above, neither Sklar, Dew, Belkin, Anderson, Dwyer nor their combination teach or make obvious a system capable of coagulating tissue with the system in a coagulation mode and ablating tissue with the system in ablation mode which combines laser pulses from multiple laser to generate a single laser output. For at least these reasons, the new independent Claim 41 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination.

Claims 43-49 all dependent on the independent Claim 41. As described above, the independent Claim 41 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination. Accordingly, Claims 43-49 are all allowable as being dependent upon an allowable base claim.

Within the previous Office Action, Claims 4, 5, 9, 10, 20-24 and 42 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,098,426 to Sklar et al. (hereinafter "Sklar") in combination with U.S. Patent No. 4,672,969 to Dew (hereinafter "Dew"), U.S. Patent No. 5,620,435 to Belkin et al. (hereinafter "Belkin"), the article entitled "Selective Photothermolysis: Precise Microsurgery by Selective Absorption of Pulsed Radiation" by R. Rox Anderson and John A. Parrish (hereinafter "Anderson") and U.S. Patent No. 5,125,922 to Dwyer (hereafter "Dwyer") and further in view of U.S. Patent No. 5,938,657 to Assa et al. (hereinafter "Assa").

The teachings of Assa have been fully characterized in a previous communications. Again, Assa fails to teach or suggest the features of combining laser pulses from a laser source comprising multiple lasers to generate a single laser output or operative condition.

Claims 4, 5, 9 and 10 are all dependent on the independent Claim 1. As described above, the independent Claim 1 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination. Accordingly, Claims 4, 5, 9 and 10 are all also allowable as being dependent upon an allowable base claim.

Claims 20-24 are all dependent on the independent Claim 17. As described above, the independent Claim 17 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination. Accordingly, Claims 20-24 are all also allowable as being dependent upon an allowable base claim.

Claim 42 is dependent on the independent Claim 41. As described above, the independent Claim 41 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination. Accordingly, Claim 42 is also allowable as being dependent upon an allowable base claim.

For the reasons given above, Applicants respectfully submit that the claims are in a condition for allowance, and allowance at an early date would be appreciated. Should the Examiner have any questions or comments, they are encouraged to call the undersigned at (408) 530-9700 to discuss the same so that any outstanding issues can be expeditiously resolved.

Respectfully submitted,
HAVERSTOCK & OWENS LLP

Dated: November 28, 2003 By: Jonathan O. Owens

Jonathan O. Owens
Reg. No.: 37,902
Attorneys for Applicant

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/018,104	02/03/1998	JAMES L. HOBART	PHAN-00100	9278

28960 7590 07/28/2003

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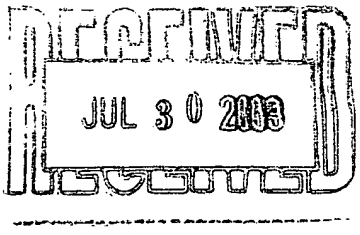
EXAMINER
SHAY, DAVID M

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 07/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.



Office Action Summary	Application No. 09/018,104	Applicant(s) Holmes et al
	Examiner d. shay	Group Art Unit 3739

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE -3- MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on May 5, 2003.

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1-14, 17-24 + 41-49 is/are pending in the application.

Of the above claim(s)_____ is/are withdrawn from consideration.

☐ Claim(s)_____ is/are allowed.

☒ Claim(s) 1-14, 17-24+41-49 is/are rejected.

☐ Claim(s)_____ is/are objected to.

☐ Claim(s)_____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on_____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on_____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number)_____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received:_____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s)._____

☐ Interview Summary, PTO-413

☐ Notice of References Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other_____

Office Action Summary

The examiner has considered applicants arguments to the following effect.

While the examiner neither disputes that the disclosure provides support for the use of two lasers in the laser source, nor that there is support for combining the two beams. In fact these teachings are supported by the cited passages at page 2 of the instant response. However, the claims rejected under 35 USC 112, first paragraph recite, in pertinent part "wherein the laser source comprises two or more lasers, each for generating laser pulses to provide the series of laser pulses and sufficient to generate ablation when the laser source is in ablation mode" this language, as understood by the examiner, requires that each laser produce ablation pulses when the source is in ablation mode. Such teaching has not been found by the examiner in the originally filed disclosure, nor is it supported by the cited passages.

Similarly the language of claim 11 "wherein the pulses of laser light are combined in an alternating fashion for generating a laser output having a predetermined absorption, wherein the predetermined absorption forms a predetermined absorption, wherein the predetermined absorption forms a predetermined coagulation depth". Requires that a property referred to as "absorption" forms the coagulation depth, which property results from the combination of the beams in an alternating fashion. The examiner has not found, nor do the cited passages support controlling the coagulation depth by a property determined by the combination of the beams in an alternating fashion.

With regard to the teachings of Dwyer and the applicability thereof to claims 17 and 41, applicant's attention is respectfully invited to Figure 3 of Dwyer et al and the attendant disclosure. As can be easily seen, Figure 3 shows two lasers (35 and 36) which are controlled by a wavelength selecting switch (38) and whose outputs are combined at beam splitter (37). This

is determined at column 4, lines 12-22 of Dwyer et al. It is noted that the pulses produced by the lasers of Dwyer et al must have both a power and duration else they would not exist.

These are the structures required by claim 17. The claim does contain a functional statement regarding the function of the control system: "for controlling generation of the laser pulses..." The examiner first notes that this recitation is not of the proper form to invoke 35 USC 112, sixth paragraph (see MPEP 2181) thus the function is accorded little weight. Secondly the functional recitation merely recites that the coagulation depth be controllable and since Dwyer et al teach that the "respective lasers are turned on and off as desired " (see column 4, lines 20 and 21) this is considered to provide the recited controllability even assuming that the claim language in question were crafted to invoke the sixth paragraph of 35 U.S.C. 112.

Regarding claim 41, applicant's attention is once again invited to Figure 3 of Dwyer et al and lines 12-22 in column 4 thereof and the structures set forth above. Additionally optical fiber 21 constitutes a "means to direct..." as recited in the claim. It is noted that the ability of the switch to provide pulses from alternating lasers renders it a "means to alternate between pulses of the first set of laser pulses and pulses of the second set of laser pulses" as claimed.

With regard to the rejection under 35 U.S.C. 103, applicant argues each reference singly with no regard to what the combined teachings would suggest to one having ordinary skill in the art. Applicant also argues, without any rationale other than the aforementioned piecemeal treatment of the applied references that a *prima facie* case of obviousness has not been made. Next applicant asserts that no suggestion within the references or "within the general knowledge of the art to combine such a large number of references." The examiner firstly notes that the number of references combined, standing alone, does not provide a showing of non-obviousness

(MPEP 2145). It is further noted that providing the combined coagulation and ablation functions in a single device is already known to be desirable, as shown by Dwyer et al and Dew, therefore to produce such a device from a device that only provided e.g. a cutting functionality at no extra cost is clearly motivated by economic considerations.

As already set forth above and in the previous explanation of the teaching of Dwyer et al, this reference clearly teaches combining the laser outputs in an alternating fashion in that first one laser is activated, then the other, both pulses being guided to a common optical path leading to an output device, such as the optical fiber. If applicant continues in this assertion, the examiner respectfully requests that the exact aspect of the claimed "combining the beams in an alternating fashion" which is perceived to be absent from Dwyer et al be specifically pointed out, that the examiner may determine the precise limitations upon which applicant is predicating the patentability of the claimed invention.

The rejections set forth in the previous office action are hereby repeated.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no support in the originally filed disclosure for each of two lasers generating pulses to generate ablation, nor combining the pulses of two sources to form a predetermined coagulation depth.

Claims 17 and 41 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Dwyer et al.

See Figure 3, and column 4 lines 12 et seq.

Claims 1-3, 6-8, 11-14, 17-19, 41, and 43-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sklar et al in combination with Dew ('969), Anderson et al, Belkin et al and Dwyer et al. Sklar et al teach a laser system including multiple lasers with a graphical interface and teach that it can be used for any type of surgery with any type of laser and that the depth of the laser action can be input and displayed. Dew ('969) teaches the use of a carbon dioxide laser operating at 10.6 microns as a cutting laser in a laser system comprised of multiple lasers and teaches that the power of a pulse determines the amount of heat deposited in the tissue and that the same type of laser can be used for cutting and coagulating. Belkin et al teach that the carbon dioxide lasers operating at 10.6 microns can be used to heat, rather than cut tissue. Anderson et al teach the way parameters such as absorptivity spot size, and pulse width interrelate to control the amount of energy absorbed by tissue. Dwyer et al teach performing surgery by alternating cutting and coagulation. It would have been obvious to the artisan of ordinary skill to use a carbon dioxide laser as taught by Dew ('969) in the graphical user interface of Sklar et al, since this is to be used with any laser, as taught by Sklar et al; to also configure the laser to coagulate as taught by Belkin et al, since this would render the device more versatile, at no extra cost; to employ the particular laser parameters claimed since these provide no unexpected result, and are within the scope of one having ordinary skill in the art as shown by Anderson et al; to alternate cutting and coagulating pulses, since this enables bloodless surgery, as taught by Dwyer et al; to employ an articulated arm with refocusing convex lenses since these are notorious in the art for

transporting infrared radiation such as that from Carbon dioxide lasers, official notice of which has already taken; and to use a galvanometer to alternate the beams, since these are notorious for moving optical components official notice which has already been taken thus producing a device such as claimed.

Claims 4, 5, 9, 10, 20-24, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sklar et al combination with Dew ('969), Anderson et al, Belkin et al, and Dwyer et al as applied to claims 1-3, 6-8, 11-14, 17-19, 41, and 43-49 are above, and further in view of Assa et al. Assa et al teach a scanning handpiece and the equivalence of carbon dioxide and Erbium YAG lasers. Thus it would have been obvious to the artisan or ordinary skill to employ and handpiece as taught by Assa et al, since this allows more consistency of treatment and to employ an erbium laser, since these are equivalent to the carbon dioxide laser, thus producing a device such as claimed.

Applicant's arguments filed May 5, 2001 have been fully considered but they are not persuasive. The arguments are not convincing for the reasons set forth above.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Shay whose telephone number is (703) 308-2215. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0944.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Shay/Dl

July 18, 2003

DAVID M. SHAY
PRIMARY EXAMINER
GROUP 330

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/018,104	02/03/1998	JAMES L. HOBART	PHAN-00100	9278

28960 7590 12/26/2002

HAVERSTOCK & OWENS LLP
162 NORTH WOLFE ROAD
SUNNYVALE, CA 94086

EXAMINER
SHAY, DAVID M

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 12/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

UNITED ST :S DEPARTMENT OF COMMERCE
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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.

EXAMINER

ART UNIT	PAPER NUMBER

DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☑ Responsive to communication(s) filed on September 30, 2002

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☑ Claim(s) 1-14,17-24,40-49 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☑ Claim(s) 1-14,17-24,40-49 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

★ U.S. GPO: 1996-404-496/40517

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no support in the originally filed disclosure for each of two lasers generating pulses to generate ablation, nor combining the pulses of two sources to form a predetermined coagulation depth.

Regard the Information Disclosure Statement filed May 13, 2001, the examiner notes that only references AA (Re 36,872 - Zair) through CS (5,190,032 -Zair) have been accompanied by copies thereof, as required by MPEP 609, thus the remaining citations - CT through GH have not been considered as no copies have been provided. The examiner further advises applicant that in contrast to the remainder of considered submissions, which relate in some way to laser application, or optics reference AI (3,854,153 - Fadler) relates to a fold away bed. Thus if applicant intended some other reference to be considered, that reference should be submitted.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 17 and 41 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Dwyer et al.

Claims 1-3, 6-8, 11-14, 17-19, 41 and 43-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sklar et al in combination with Dew ('969), Anderson et al, Belkin et al and Dwyer et al. Sklar et al teach a laser system including multiple lasers with a graphical interface and teach that it can be used for any type of surgery with any type of laser and that the depth of the laser action can be input and displayed. Dew ('969) teaches the use of a carbon dioxide laser operating at 10.6 microns as a cutting laser in a laser system comprised of multiple lasers and teaches that the power of a pulse determines the amount of heat deposited in the tissue and that the same type of laser can be used for cutting and coagulating. Belkin et al teach that carbon dioxide lasers operating 10.6 microns can be used to heat, rather than cut tissue. Anderson et al teach the way parameters such as absorptivity spot size, and pulse width interrelate to control the amount of energy absorbed by tissue. Dwyer et al teach performing surgery by alternating cutting and coagulation. It would have been obvious to the artisan of ordinary skill to use a carbon dioxide laser as taught by Dew ('969) in the graphical user interface of Sklar et al, since this is to be used with any laser, as taught by Sklar et al, to also configure the laser to coagulate as taught by Belkin et al, since this would render the device more versatile, at no extra cost and to employ the particular laser parameters claimed since these provide no unexpected result., and are within the scope of one having ordinary skill in the art as shown to by Anderson et al to alternate cutting and coagulating pulses, since this enables bloodless surgery, as taught by Dwyer et al; employ an articulated arm with refocussing convex lenses since these are notorious in the art for transporting infrared radiation such as that from Carbon dioxide lasers, official notice of which has already

taken and to use a galvanometer to alternate the beams, since these are notorious for moving optical components official notice which has already been taken thus producing a device such as claimed.

Claims 4, 5, 9, 10, 20-24, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sklar et al in combination with Dew ('969), Anderson et al, Belkin et al and Dwyer et al as applied to claims 1-3, 6-8, 11-14, 17-19, 41, and 43-49 above, and further in view of Assa et al. Assa et al teach a scanning handpiece and the equivalence of carbon dioxide and Erbium YAG lasers. Thus it would have been obvious to the artisan or ordinary skill to employ an handpiece as taught by Assa et al, since this allows more consistency of treatment and to employ an erbium laser, since these are equivalent to the carbon dioxide laser, thus producing a device such as claimed.

Applicant argues that "Dwyer does not teach combining light from multiple lasers at all". The examiner must disagree, Dwyer et al clearly teach and actually claim the alternate production and direction to the single output of the device, two beams from two separate lasers. The examiner can see no reason why this cannot be considered "combining light from multiple lasers" and applicant has proffered absolutely no rational whatsoever upon which such a distinction can be predicated. As such the unsupported assertion of applicant that the beams of Dwyer et al are not combined is not persuasive, the fact that the instant invention contemplates the same type of beam combination notwithstanding. It is noted that since the lasers of Dwyer et al are switched on and off to produce alternating pulses of light, they are pulsed lasers.

Regarding the combination rejections, applicant merely argues the applied references separately, completely disregarding the teachings of the combination as a whole. These arguments are not convincing.

Any inquiry concerning this communication should be directed to David Shay at telephone number (703) 308-2215.

DAVID M. SHAY
PRIMARY EXAMINER
GROUP 330

David Shay:lf
December 18, 2002